No. 24-1939 (L)

United States Court of Appeals
for the Fourth Circuit

ABBVIE, INC., (a Delaware corporation); ALLERGAN, INC., (a Delaware corporation); DURATA THERAPEUTICS, INC., (a Delaware corporation); ABBVIE PRODUCTS LLC, (a Georgia limited liability company); APTALIS PHARMA US, INC., (a Delaware corporation); PHARMACYCLICS LLC, (a Delaware limited liability company); ALLERGAN SALES, LLC, (a Delaware limited liability company),

Plaintiffs - Appellants,

and

NOVARTIS PHARMACEUTICALS CORPORATION; PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA; ASTRAZENECA PHARMACEUTICALS LP,

Plaintiffs,

v.

ANTHONY G. BROWN, in his official capacity as Attorney General of the State of Maryland; KRISTOPHER RUSINKO, in his official capacity as Board President of the Maryland Board of Pharmacy; DAPHANIE ROBINSON, in her official capacity as a member of the Maryland Board of Pharmacy; ADETORO ORIAIFO, in his official capacity as a member of the Maryland Board of Pharmacy; KRISTEN FINK, in her official capacity as a member of the Maryland Board of Pharmacy; KAREN SLAGLE, in her official capacity as a member of the Maryland Board of Pharmacy; BRENDA OLIVER, in her official capacity as a member of the Maryland Board of Pharmacy; KARLA EVANS, in her official capacity as a member of the Maryland Board of Pharmacy; JAVIER VAZQUEZ, in his official capacity as a member of the Maryland Board of Pharmacy; AKESH PATEL, in his official capacity as a member of the Maryland Board of Pharmacy; KEVIN MORGAN, in his official capacity as a member of the Maryland Board of Pharmacy; JENNIFER HARDESTY, in her official capacity as a member of the Maryland Board of Pharmacy; PEGGY GLASCOE

GEIGHER, in her official capacity as a member of the Maryland Board of Pharmacy; NEIL LEIKACH, in his official capacity as a member of the Maryland Board of Pharmacy; MARYLAND BOARD OF PHARMACY/PRESIDENT,

Defendants - Appellees.

No. 24-1949

NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiff - Appellant,

and

ABBVIE, INC., (a Delaware corporation); ALLERGAN, INC., (a Delaware corporation); DURATA THERAPEUTICS, INC., (a Delaware corporation); ABBVIE PRODUCTS LLC, (a Georgia limited liability company); APTALIS PHARMA US, INC., (a Delaware corporation); PHARMACYCLICS LLC, (a Delaware limited liability company); ALLERGAN SALES, LLC, (a Delaware limited liability company); PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA; ASTRAZENECA PHARMACEUTICALS LP,

Plaintiffs,

v.

ANTHONY G. BROWN, in his official capacity as Attorney General of the State of Maryland; KRISTOPHER RUSINKO, in his official capacity as Board President of the Maryland Board of Pharmacy; DAPHANIE ROBINSON, in her official capacity as a member of the Maryland Board of Pharmacy; ADETORO ORIAIFO, in his official capacity as a member of the Maryland Board of Pharmacy; KRISTEN FINK, in her official capacity as a member of the Maryland Board of Pharmacy; KAREN SLAGLE, in her official capacity as a member of the Maryland Board of Pharmacy; BRENDA OLIVER, in her official capacity as a member of the Maryland Board of Pharmacy; KARLA EVANS, in her official capacity as a member of the Maryland Board of Pharmacy; JAVIER VAZQUEZ, in his official capacity as a member of the Maryland Board of Pharmacy; AKESH PATEL, in his official capacity as a member of the Maryland Board of Pharmacy; KEVIN MORGAN, in his official capacity as a member of the Maryland Board

of Pharmacy; JENNIFER HARDESTY, in her official capacity as a member of the Maryland Board of Pharmacy; PEGGY GLASCOE GEIGHER, in her official capacity as a member of the Maryland Board of Pharmacy; NEIL LEIKACH, in his official capacity as a member of the Maryland Board of Pharmacy; MARYLAND BOARD OF PHARMACY/PRESIDENT,

Defendants - Appellees.

No. 24-1978

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff - Appellant,

and

ABBVIE, INC., (a Delaware corporation); ALLERGAN, INC., (a Delaware corporation); DURATA THERAPEUTICS, INC., (a Delaware corporation); ABBVIE PRODUCTS LLC, (a Georgia limited liability company); APTALIS PHARMA US, INC., (a Delaware corporation); PHARMACYCLICS LLC, (a Delaware limited liability company); ALLERGAN SALES, LLC, (a Delaware limited liability company); NOVARTIS PHARMACEUTICALS CORPORATION; ASTRAZENECA PHARMACEUTICALS LP,

Plaintiffs,

v.

ANTHONY G. BROWN, in his official capacity as Attorney General of the State of Maryland; KRISTOPHER RUSINKO, in his official capacity as Board President of the Maryland Board of Pharmacy; DAPHANIE ROBINSON, in her official capacity as a member of the Maryland Board of Pharmacy; ADETORO ORIAIFO, in his official capacity as a member of the Maryland Board of Pharmacy; KRISTEN FINK, in her official capacity as a member of the Maryland Board of Pharmacy; KAREN SLAGLE, in her official capacity as a member of the Maryland Board of Pharmacy; BRENDA OLIVER, in her official capacity as a member of the Maryland Board of Pharmacy; KARLA EVANS, in her official capacity as a member of the Maryland Board of Pharmacy; JAVIER VAZQUEZ, in his official capacity as a member of the Maryland Board of Pharmacy; AKESH PATEL, in his official

capacity as a member of the Maryland Board of Pharmacy; KEVIN MORGAN, in his official capacity as a member of the Maryland Board of Pharmacy; JENNIFER HARDESTY, in her official capacity as a member of the Maryland Board of Pharmacy; PEGGY GLASCOE GEIGHER, in her official capacity as a member of the Maryland Board of Pharmacy; NEIL LEIKACH, in his official capacity as a member of the Maryland Board of Pharmacy; MARYLAND BOARD OF PHARMACY/PRESIDENT,

Defendants - Appellees.

On Appeal from the United States District Court
for the District of Maryland,
No. 1:24-cv-01557-MJM
Judge Matthew J. Maddox

APPELLANTS' OPENING BRIEF

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Counsel for Plaintiff – Appellant Pharmaceutical Research and Manufacturers of America

December 18, 2024

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

DISCLOSURE STATEMENT

- In civil, agency, bankruptcy, and mandamus cases, a disclosure statement must be filed by **all** parties, with the following exceptions: (1) the United States is not required to file a disclosure statement; (2) an indigent party is not required to file a disclosure statement; and (3) a state or local government is not required to file a disclosure statement in pro se cases. (All parties to the action in the district court are considered parties to a mandamus case.)
- In criminal and post-conviction cases, a corporate defendant must file a disclosure statement.
- In criminal cases, the United States must file a disclosure statement if there was an organizational victim of the alleged criminal activity. (See question 7.)
- Any corporate amicus curiae must file a disclosure statement.
- Counsel has a continuing duty to update the disclosure statement.

No. 24-1939L Caption: AbbVie, Inc. et al. v. Anthony Brown et al.

Pursuant to FRAP 26.1 and Local Rule 26.1,

AbbVie Inc.; Allergan, Inc.; Durata Therapeutics, Inc.; AbbVie Products LLC;
(name of party/amicus)

Aptalis Pharma US, Inc.; Pharmacyclics LLC; and Allergan Sales LLC

who is Appellants, makes the following disclosure:
(appellant/appellee/petitioner/respondent/amicus/intervenor)

1. Is party/amicus a publicly held corporation or other publicly held entity? ☑ YES ☐ NO

2. Does party/amicus have any parent corporations? ☑ YES ☐ NO
If yes, identify all parent corporations, including all generations of parent corporations:

3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity? ☑ YES ☐ NO
If yes, identify all such owners:

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation? ☐YES ☑NO
If yes, identify entity and nature of interest:

5. Is party a trade association? (amici curiae do not complete this question) ☐YES ☑NO
If yes, identify any publicly held member whose stock or equity value could be affected substantially by the outcome of the proceeding or whose claims the trade association is pursuing in a representative capacity, or state that there is no such member:

6. Does this case arise out of a bankruptcy proceeding? ☐YES ☑NO
If yes, the debtor, the trustee, or the appellant (if neither the debtor nor the trustee is a party) must list (1) the members of any creditors' committee, (2) each debtor (if not in the caption), and (3) if a debtor is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of the debtor.

7. Is this a criminal case in which there was an organizational victim? ☐YES ☑NO
If yes, the United States, absent good cause shown, must list (1) each organizational victim of the criminal activity and (2) if an organizational victim is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of victim, to the extent that information can be obtained through due diligence.

Signature: /s/ Matthew S. Owen Date: 12/18/2024

Counsel for: Appellants

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AbbVie, Inc. et al. v. Anthony Brown et al.
No. 24-1939 (L)

Does party/amicus have any parent corporations? If yes, identify all parent corporations, including all generations of parent corporations:

Allergan, Inc. is 100% owned by Allergan Finance, LLC; Durata Therapeutics, Inc. is 100% owned by Allergan W.C. Holding Inc.; AbbVie Products LLC is 100% owned by AbbVie Inc.; Aptalis Pharma US, Inc. is 100% owned by Allergan Sales, LLC; Pharmacyclics LLC is 100% owned by AbbVie Inc.; Allergan Sales, LLC is 51.8% owned by Allergan Holdings, Inc. and 48.2% owned by Allergan Holdco US, Inc.; and AbbVie Inc. is the ultimate parent of each of the other aforementioned entities.

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

DISCLOSURE STATEMENT

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- In criminal and post-conviction cases, a corporate defendant must file a disclosure statement.
- In criminal cases, the United States must file a disclosure statement if there was an organizational victim of the alleged criminal activity. (See question 7.)
- Any corporate amicus curiae must file a disclosure statement.
- Counsel has a continuing duty to update the disclosure statement.

No. 24-1949 Caption: Novartis Pharmaceuticals Corporation v. Anthony Brown et al.

Pursuant to FRAP 26.1 and Local Rule 26.1,

Novartis Pharmaceuticals Corporation
(name of party/amicus)

who is Appellant, makes the following disclosure:
(appellant/appellee/petitioner/respondent/amicus/intervenor)

1. Is party/amicus a publicly held corporation or other publicly held entity? ☑ YES ☐ NO

2. Does party/amicus have any parent corporations? ☑ YES ☐ NO
If yes, identify all parent corporations, including all generations of parent corporations:

Novartis Finance Corporation

3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity? ☑ YES ☐ NO
If yes, identify all such owners:
Novartis AG, as Novartis Pharmaceuticals Corporation is its indirect, wholly owned subsidiary.

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation? ☐YES ☑NO
If yes, identify entity and nature of interest:

5. Is party a trade association? (amici curiae do not complete this question) ☐YES ☑NO
If yes, identify any publicly held member whose stock or equity value could be affected substantially by the outcome of the proceeding or whose claims the trade association is pursuing in a representative capacity, or state that there is no such member:

6. Does this case arise out of a bankruptcy proceeding? ☐YES ☑NO
If yes, the debtor, the trustee, or the appellant (if neither the debtor nor the trustee is a party) must list (1) the members of any creditors' committee, (2) each debtor (if not in the caption), and (3) if a debtor is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of the debtor.

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If yes, the United States, absent good cause shown, must list (1) each organizational victim of the criminal activity and (2) if an organizational victim is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of victim, to the extent that information can be obtained through due diligence.

Signature: /s/ Catherine E. Stetson Date: December 18, 2024

Counsel for: Novartis Pharmaceuticals Corp.

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

DISCLOSURE STATEMENT

- In civil, agency, bankruptcy, and mandamus cases, a disclosure statement must be filed by **all** parties, with the following exceptions: (1) the United States is not required to file a disclosure statement; (2) an indigent party is not required to file a disclosure statement; and (3) a state or local government is not required to file a disclosure statement in pro se cases. (All parties to the action in the district court are considered parties to a mandamus case.)
- In criminal and post-conviction cases, a corporate defendant must file a disclosure statement.
- In criminal cases, the United States must file a disclosure statement if there was an organizational victim of the alleged criminal activity. (See question 7.)
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- Counsel has a continuing duty to update the disclosure statement.

No. 24-1939L Caption: AbbVie, Inc. et al. v. Anthony Brown et al.

Pursuant to FRAP 26.1 and Local Rule 26.1,

Pharmaceutical Research and Manufacturers of America
(name of party/amicus)

who is appellant, makes the following disclosure:
(appellant/appellee/petitioner/respondent/amicus/intervenor)

1. Is party/amicus a publicly held corporation or other publicly held entity? ☐ YES ☑ NO

2. Does party/amicus have any parent corporations? ☐ YES ☑ NO
If yes, identify all parent corporations, including all generations of parent corporations:

3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity? ☐ YES ☑ NO
If yes, identify all such owners:

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation? ☐YES ☑NO
If yes, identify entity and nature of interest:

5. Is party a trade association? (amici curiae do not complete this question) ☑YES ☐NO
If yes, identify any publicly held member whose stock or equity value could be affected substantially by the outcome of the proceeding or whose claims the trade association is pursuing in a representative capacity, or state that there is no such member:

See Attachment A

6. Does this case arise out of a bankruptcy proceeding? ☐YES ☑NO
If yes, the debtor, the trustee, or the appellant (if neither the debtor nor the trustee is a party) must list (1) the members of any creditors' committee, (2) each debtor (if not in the caption), and (3) if a debtor is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of the debtor.

7. Is this a criminal case in which there was an organizational victim? ☐YES ☑NO
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Signature: /s/ Abid R. Qureshi Date: 12/18/2024

Counsel for: Pharmaceutical Research and Manufacturers of America

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Attachment A –

Members of Pharmaceutical Research and Manufacturers of America

Alkermes plc.

Amgen Inc.

Astellas Pharma

Bayer Corporation

Biogen

BioMarin Pharmaceutical Inc.

Boehringer Ingelheim Pharmaceuticals, Inc.

Bristol Myers Squibb

CSL

Daiichi Sankyo, Inc.

Eisai Inc.

Eli Lilly and Company

EMD Serono

Genentech

Genmab US, Inc.

Gilead Sciences, Inc.

GlaxoSmithKline

Incyte Corporation

Ipsen Biopharmaceuticals, Inc.

Johnson & Johnson

Lundbeck LLC

Merck & Co., Inc.

Neurocrine Biosciences, Inc.

Novartis Pharmaceuticals Corporation

Novo Nordisk Inc.

Otsuka America Pharmaceutical, Inc.

Pfizer Inc.

Sage Therapeutics, Inc.

Sanofi

Takeda Pharmaceuticals USA, Inc.

UCB

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JURISDICTIONAL STATEMENT

The district court has subject-matter jurisdiction under 28 U.S.C. § 1331 because Appellants bring federal constitutional challenges to a Maryland state law. This Court has appellate jurisdiction over these consolidated appeals from the district court's order denying Appellants' motion for a preliminary injunction under 28 U.S.C. § 1292(a)(1). AbbVie timely filed its notice of appeal on September 25, 2024; Novartis timely filed its notice of appeal on October 1, 2024; and PhRMA timely filed its notice of appeal on October 3, 2024. Appellants therefore noticed their appeals within 30 days of the district court's order of September 5, 2024. Fed. R. App. 4.

ISSUES PRESENTED

In 1992, Congress created a healthcare initiative called the "340B Program." That Program requires drug manufacturers, as a condition of their participation in Medicaid and Medicare Part B, to offer certain drugs at significantly discounted prices to a list of 15 specifically enumerated healthcare providers. Two courts of appeals have confirmed that manufacturers may impose reasonable conditions on those offers—including that their drugs not be delivered at discounted prices to an unlimited number of pharmacies and requiring the submission of claims data. Maryland's H.B. 1056 grafts new requirements onto that federal statute. In particular, Maryland intends to compel manufacturers, under threat of civil and criminal penalties, to give away more discounted drugs, under more onerous conditions than Congress requires—all in exchange for nothing.

Appellants moved to preliminarily enjoin H.B. 1056, but the district court denied relief. The issues presented are:

1. Whether Appellants are likely to succeed in showing H.B. 1056 intrudes on a federally preempted field and conflicts with federal law by engrafting new requirements on

the federal 340B statute to expand manufacturers' obligations beyond the scope delineated by Congress, changing the conditions of participation in federal healthcare programs, and adding a new state enforcement scheme to the unitary federal scheme enacted by Congress.

2. Whether Appellants are likely to succeed in showing H.B. 1056 compels manufacturers to transfer their products at significant discounts to private pharmacies for no public use, in violation of the Takings Clause.
3. Whether Appellants are likely to succeed in showing H.B. 1056 regulates transactions occurring wholly out of state in violation of the extraterritoriality principles embodied in the United States Constitution.
4. Whether the irreparable harm and equities factors likewise favor an injunction.

INTRODUCTION

The federal 340B Program requires participating pharmaceutical manufacturers to "offer" certain drugs at heavily discounted prices to a select list of government-approved healthcare providers. 42 U.S.C. § 256b(a)(1). Congress tailored the Program to balance competing interests: providing discounts to certain providers, preventing abuse of the Program, and encouraging manufacturers to participate in the Program and other linked government healthcare programs.

In recent years, the enumerated healthcare providers—or "covered entities"—began seeking to circumvent those restrictions by entering into a vast number of arrangements with for-profit retail pharmacies to purchase 340B-priced drugs and distribute them. Given the threat of abuse those arrangements pose, manufacturers independently implemented policies regarding the use of contract pharmacies. In response, the federal Department of Health and Human Services (or "HHS") sought to force manufacturers to provide 340B-priced drugs to an unlimited number of contract pharmacies. But federal appellate courts have made clear that the federal statute requires a manufacturer only to "offer" covered drugs at the ceiling price, and that offer may include

reasonable conditions on the use of contract pharmacies, including limits on their number and requirements to provide claims data. *See Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 702-07 (3d Cir. 2023); *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 461-64 (D.C. Cir. 2024). If the provider accepts the terms of that offer and the drugs are "purchased by" the provider, the manufacturer then provides the ceiling price. *See Novartis*, 102 F.4th at 461-62. Where a provider does not assent to the terms, no obligation to provide the federal ceiling price exists. In short, manufacturers owe only the obligation enumerated in the statute to covered entities and none at all to contract pharmacies. *See Sanofi*, 58 F.4th at 707; *Novartis*, 102 F.4th at 462-64.

This case concerns Maryland's attempt to achieve what the courts told HHS it could not. Earlier this year, Maryland enacted H.B. 1056, which forces pharmaceutical manufacturers to provide 340B pricing on their drugs provided to contract pharmacies, even where there has been no qualifying 340B purchase, i.e., offer and acceptance, under federal law. Under H.B. 1056, manufacturers cannot "deny, restrict, prohibit, discriminate against, or otherwise limit the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with

… a covered entity." H.B. 1056, § 12-6C-09.1(C)(1). Maryland is thus requiring of manufacturers *precisely* what multiple courts concluded HHS could not.

Below, AbbVie, Novartis Pharmaceuticals Corporation, and Pharmaceutical Research and Manufacturers of America ("PhRMA") (collectively, "Appellants") separately sought to preliminarily enjoin H.B. 1056. All Appellants argued that H.B. 1056 is both field- and conflict-preempted because it intrudes upon the wholly federal field of 340B pricing and eligibility with its own substantive requirements and penal scheme, and also obstructs Congress's purposes in the 340B statute by, among other things, compelling the 340B price when federal law does not. AbbVie additionally argued that H.B. 1056 works an unconstitutional physical taking because it forces manufacturers to transfer their products to private, for-profit pharmacies at below-market prices, on pain of civil and criminal penalties. And Novartis and PhRMA both contended that H.B. 1056 unconstitutionally regulates wholly out-of-state transactions.

Although the Maryland Attorney General could not decide whether the law regulates the price of 340B drugs or only their delivery, the

district court still denied relief. The court also summarily concluded that the public interest and equities weighed against enjoining the law. That decision directly conflicts with a recent decision of another district court in this circuit that preliminarily enjoined, as conflict-preempted, West Virginia's substantially similar law. *See PhRMA v. Morrisey*, 2024 WL 5147643, at *7-12 (S.D. W. Va Dec. 17, 2024) (holding that law was preempted because it threatened the federal government's enforcement authority, contrary to Supreme Court precedent, and severely hampered manufacturers' ability to access the federal enforcement scheme).

Because Appellants will suffer irreparable injury if Maryland enforces H.B. 1056, and because patients' access to and prices paid for drugs will remain unchanged, the district court's decision should be reversed.

STATEMENT OF THE CASE

A. The 340B Pricing Program.

In 1992, Congress enacted Section 340B of the Public Health Service Act, establishing the "340B Program." *See* 42 U.S.C. § 256b. The statute requires pharmaceutical manufacturers participating in Medicare Part B and Medicaid to offer products to a specified list of

health providers at significantly discounted prices. *Id.* §§ 256b(a)(1), (a)(4).

The 340B Program works as follows: In exchange for participation in federal Medicaid and Medicare Part B programs, the statute requires manufacturers to "offer" their products to each "covered entity … for purchase at or below the applicable ceiling price." *Id.* § 256b(a)(1). The enumerated "covered entit[ies]" include, among others, federally qualified health centers and rural hospitals. *Id.* § 256b(a)(4). The statutorily enumerated list of covered entities does not include contract pharmacies. *See id.*

The "ceiling price" is set by a statutory formula and results in significant price reductions, ranging from 23.1% to more than *99.9%* of the average market price for a drug—often requiring that manufacturers sell their medicine for as little as one penny per unit. *Id.* § 1396r-8(c); *id.* § 256b(a)(1).

Should the covered entity accept the terms of the manufacturer's 340B "offer," it can "purchase" the drugs at the ceiling price. *Id.* § 256b(a)(1). But if the covered entity decides to not "assent to the

[offered] terms," there is no "purchase" to which the ceiling price applies. *Novartis*, 102 F.4th at 460 (quoting 1 *Corbin on Contracts* § 1.11 (2023)).

The federal statute imposes several substantive rules that define the manufacturers' and covered entities' obligations under the Program.

First, the statute prohibits covered entities from selling or transferring drugs they purchased at the 340B price to anyone who is not a patient of the entity—often referred to as "diversion." 42 U.S.C. § 256b(a)(5)(B). By limiting 340B sales to only covered entities for their patients, Congress attempted to ensure that the Program did not simply become a buy-low sell-high scheme for those with a profit motive.

Second, covered entities may not cause state Medicaid programs to demand rebates from manufacturers on a unit of drug purchased at a 340B price—those are forbidden "duplicate discounts." *Id.* § 256b(a)(5)(A)(i). Otherwise, a manufacturer would be required to provide two pricing discounts on the same product.

Third, covered entities must permit both HHS's Secretary and manufacturers to audit their records that directly pertain to the entity's compliance with the prohibitions on diversion and duplicate discounting. *Id.* § 256b(a)(5)(C).

Congress vested HHS with authority to enforce and administer the 340B Program. *Astra USA, Inc. v. Santa Clara Cnty., Cal.*, 563 U.S. 110, 120-21 (2011). The agency can impose civil monetary penalties if a manufacturer is found to have charged a covered entity above the ceiling price. 42 U.S.C. § 256b(d)(1)(B)(vi). HHS may also sanction covered entities for diversion and duplicate discounting. *Id.* § 256b(d)(2)(B)(v).

HHS's enforcement authority is exclusive, with review only by federal courts. *Astra*, 563 U.S. at 117; 42 U.S.C. § 256b(d)(3)(C). In *Astra*, the Supreme Court held that, by vesting enforcement authority solely in HHS, Congress impliedly withheld from covered entities a private right of action to enforce the 340B Program's requirements against manufacturers. 563 U.S. at 117. "[S]preading the enforcement burden" of the 340B Program "is hardly what Congress contemplated when it 'centralized enforcement in the government,'" the Court explained. *Id.* at 119. Rather, "Congress made HHS administrator of both the Medicaid Drug Rebate Program and the 340B Program" because "the interdependent nature of the two programs' requirements means that an adjudication of rights under one program must proceed with an eye towards any implications for the other." *Id.* at 120. Thus, auxiliary

enforcement mechanisms beyond those contemplated in the statute would "undermine the agency's efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Id.*

HHS's component agency, the Health Resources and Services Administration ("HRSA") established both an informal "good faith" conferral process and a more formal proceeding referred to as Administrative Dispute Resolution ("ADR"). If the good-faith conferral process does not work, the next step is to ask HRSA to enforce the statute or, for certain specified claims, proceed through ADR. 85 Fed. Reg. 80632, 80638 (Dec. 14, 2020). HRSA recently finalized a new ADR Rule to settle disputes regarding the Program's requirements. 89 Fed. Reg. 28643 (Apr. 19, 2024). That rule sets out a process for initiating claims, 42 C.F.R. §§ 10.21(b), (d), describes the types of claims permitted, *id.* § 10.21(a), establishes an "ADR Panel" to adjudicate claims, 42 C.F.R. § 10.20, and lays out specific procedures that the ADR Panel will follow, 42 C.F.R. §§ 10.21-24. Covered entities have used this process—sometimes to raise disputes with manufacturers over contract pharmacies' role. *See, e.g.*, JA139-153; JA155-164.

B. Contract Pharmacies.

1. HRSA's Contract-Pharmacy Guidance.

In 1996, HRSA issued guidance opining that covered entities lacking an in-house dispensing pharmacy could contract with a *single* outside pharmacy to dispense 340B-priced drugs to their patients. 61 Fed. Reg. 43549, 43550-43555 (Aug. 23, 1996). But to avoid unlawful diversion, HRSA assumed that the covered entity would maintain title to those drugs and that the pharmacy would remain an agent of the covered entity. *Id.* HRSA also clarified this guidance created "no new law" and "no new rights or duties." *Id.* at 43550. The 340B Program proceeded accordingly for nearly a decade and a half.

The status quo changed abruptly in 2010. HRSA released new guidance that purported to permit *all* covered entities—even those with their own in-house pharmacy—to contract with an *unlimited* number of contract pharmacies, rather than just one local pharmacy. 75 Fed. Reg. 10272, 10273 (March 5, 2010). Yet like the 1996 guidance, the 2010 guidance claimed that it did not "impose[] additional burdens upon manufacturers" or "create[] any new rights for covered entities under the law." *Id.*

In the following decade, the number of contract pharmacies exploded from about 1,300 to 23,000. *Novartis*, 102 F.4th at 457. That should surprise no one: The more contract pharmacies a covered entity uses, the higher its profits from the sale of those drugs typically at *full price*. JA431-432. And contract pharmacies—often multi-billion-dollar, for-profit companies like CVS and Walgreens—generate significant profits by sharing in the "spread" from selling 340B-priced drugs at full or higher prices to pharmacy customers and/or seeking full commercial reimbursement from the patients' insurance plans. *Novartis*, 102 F.4th at 457-59 (noting that covered entities, contract pharmacies, and third-party administrators "often divvy up the spread" and have "a financial incentive to catalog as many prescriptions as possible as eligible for the discount"). Covered entities "pay flat fees [to the contract pharmacies] for each eligible 340B prescription." JA674. "[F]lat fees range[] from $0 to $1,750 per eligible 340B prescription." JA675 (n.39). Some covered entities even pay "a fee based on a percentage of revenue generated for each 340B prescription." JA674. So important are 340B profits to pharmacy chains that CVS and Walgreens listed manufacturers' revised

pharmacy policies as a material risk to their business.[1]

2. The Replenishment Model.

HRSA's nonbinding and shifting guidance permitted covered entities and contract pharmacies to maximize their arbitrage profits and, concerningly, dispense drugs purchased at the 340B price to customers who are not covered-entity patients. At 340B's beginning, contract pharmacies maintained a separate, segregated stock of 340B-priced drugs over which the covered entity maintained title, and the pharmacy dispensed to the covered entity's patients on its behalf. That is no longer true today. In most contract-pharmacy arrangements, 340B-priced drugs are mixed with the pharmacy's general inventory and title transfers to the pharmacy. JA174-176 (¶¶ 6–12); JA218 (¶ 11); JA791-792; JA819-822; JA826-828; JA829-830; JA553-557.

Today, most contract pharmacies, including in Maryland, operate under what is called the "replenishment model." *E.g.*, JA174-175 (¶ 7); JA215-218 (¶¶ 3–11). Under this model, the contract pharmacy fills all

[1] *See* CVS Pharmacy 10-K (2022), at 22, https://tinyurl.com/mrykrxj8 (explaining that a reduction in contract pharmacy arrangements "could materially and adversely affect the Company"); Walgreens, Inc. 10-K (2022), at 29, https://tinyurl.com/4ks6mf3s (similar).

prescriptions using its own inventory (which comprises co-mingled drugs purchased at the commercial price and the 340B price) to all individuals at the point of sale. The pharmacy does not determine at the point-of-purchase whether the individual receiving the drug is a covered entity's patient—meaning that covered-entity patients almost never receive the lower price. Only later does the pharmacy (with the help of its financially interested "third-party vendor or administrator") determine through a black-box algorithm which dispenses *may* have been to a purportedly 340B-eligible patient. JA174-175 (¶ 7); JA216 (¶¶ 4–6); JA765-767 (¶ 8a–d); *Morrisey*, 2024 WL 5147643, at *2.

Once sufficient eligible dispenses for a particular drug accumulate under that algorithm, the covered entity orders additional quantities of that drug at the 340B price for the contract pharmacy. JA174-175 (¶ 7); JA215-218 (¶¶ 3–11). Typically, though, the contract pharmacy or its third-party administrator places the order using the covered entity's account, and sometimes without the covered entity's knowledge. JA176-177 (¶¶ 12–13). Once the contract pharmacy receives the order, the cycle repeats: 340B-priced drugs are "placed on the shelf, become[] 'neutral

inventory,' and may be dispensed to any subsequent patient"—340B or not. JA218 (¶ 11).[2]

This arrangement has led to a significant uptick in abuse. The HHS Office of Inspector General has found that contract-pharmacy arrangements create a greater risk of 340B-priced drugs being dispensed to customers who are not covered entity patients. HHS Office of Inspector General, OEI-05-13-00431, Mem. Report: *Contract Pharmacy Arrangements in the 340B Program* (2014), at 1-2, https://tinyurl.com/y5rz5nxj. That is because the contract pharmacies' 340B criteria used for the algorithm are often materially overinclusive. JA174-175 (¶ 7); JA766 (¶ 8b). This enables the covered entity and its pharmacies to maximize their arbitrage profits. Indeed, "[t]he covered entity, the pharmacy, and the third-party administrator often divvy up the spread between the discounted price and the higher insurance reimbursement rate" and thus each actor "has a financial incentive to

[2] Contract pharmacies often take title themselves, and do not maintain an agency relationship with the covered entities. JA174, JA176, JA177 (¶¶ 6, 11, 14, 16).

catalog as many prescriptions as possible as eligible for the discount." *Novartis*, 102 F.4th at 457-58.

Nor has the contract-pharmacy explosion resulted in increased care to the needy or lower costs for patients. Among the 340B hospitals surveyed by the U.S. Government Accountability Office, a vast number of covered entities admit that they do not pass on *any* discounts to patients at contract pharmacies—and others admit that they do so only rarely. JA684, JA692-693; JA433. Indeed, industry experts have observed that needy patients scarcely benefit from expansions in the 340B Program and many patients see no real benefit at all. JA446; JA546. Some have even suggested that charity care to the needy has declined, with a majority of 340B hospitals providing even less charity care, on average, than ordinary hospitals. JA490-493; JA520.

3. Manufacturers' Policies And Resulting Litigation.

Beginning in 2020, drug manufacturers independently began to adopt contract-pharmacy policies to protect against growing abuses. These policies constitute material terms of the 340B "offer" manufacturers make to covered entities. For example, AbbVie's current policy continues to offer covered entities unlimited 340B drugs at or

below the ceiling price. JA193-194. But AbbVie will not provide 340B-priced drugs to unlimited, third-party contract pharmacies that serve hospital-type covered entities. JA193. Instead, consistent with the 1996 Guidelines, AbbVie permits 340B orders from one contract pharmacy location if the hospital covered entity lacks an in-house pharmacy and the contract pharmacy is located within 40 miles of the covered entity. JA193. Federal grantees are excepted from this policy. JA194. If a hospital covered entity is unable to identify an eligible contract pharmacy within 40 miles, AbbVie will work with the covered entity to identify a suitable alternative. JA193. That policy satisfies AbbVie's statutory obligation to "offer" its drugs to covered entities on reasonable terms. *Novartis*, 102 F.4th at 464.

In response, HHS issued an Advisory Opinion in December 2020 declaring that Section 340B requires manufacturers to transfer 340B-priced drugs to an unlimited number of contract pharmacies. HHS, Off. of the Gen. Counsel, Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program (Dec. 30, 2020), at 3, https://tinyurl.com/ycy2aujr. A few months later, the government began sending manufacturers with contract-pharmacy policies violation letters

purporting to enforce the 340B statute, stating such policies resulted in "overcharges." The 2020 Advisory Opinion was ultimately withdrawn after a federal district court held it unlawful. *See AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47 (D. Del. 2021).

Since then, both the Third Circuit and the D.C. Circuit have also broadly upheld manufacturers' contract-pharmacy policies as lawful and consistent with the 340B statute. *Sanofi*, 58 F.4th at 704, 707 ("Congress never said that drug makers must deliver discounted Section 340B drugs to an unlimited number of contract pharmacies."); *Novartis*, 102 F.4th at 464 ("[S]ection 340B does not categorically prohibit manufacturers from imposing conditions on the distribution of covered drugs to covered entities").

C. The Maryland Law.

In May 2024, Maryland's governor signed into law H.B. 1056. Its main feature is § 12-6C-09.1(C)(1), which states: "[A] 340B manufacturer may not directly or indirectly deny, restrict, prohibit, discriminate against, or otherwise limit the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with or otherwise authorized by a covered entity to receive 340B drugs on behalf of the

covered entity…." H.B. 1056, § 12-6C-09.1(C)(1). The phrase "340B drug" is defined by reference to its price—*i.e.*, the federal ceiling price. *Id.* § 12-6C-09.1(A)(4)(I)(2). Thus, the defining feature of the statute is the *price* at which Appellants must provide such access. It is undisputed that pharmacies otherwise have access to Appellants' products at commercial prices and that Appellants will deliver their products to pharmacies when ordered at such rates. The question, therefore, is not one of pharmacy or patient access, but of price.

H.B. 1056 prescribes a variety of penalties and punishments for noncompliance. Each violation constitutes a violation of Maryland's Consumer Protection Act, which authorizes the Attorney General to seek injunctive relief, civil penalties, and criminal sanctions. *See id.* § 12-6C-09.1(D)(1)(I)(1); Md. Code Ann., Com. Law §§ 13-406, -410 to -411. H.B. 1056 also imposes fines of $5,000 per violation—and clarifies that *each package* of noncompliant 340B drugs constitutes a separate violation. H.B. 1056, §§ 12-6C-09.1(D)(2)(I), (D)(4). The statute further empowers the Maryland Board of Pharmacy to discipline certain violators and revoke relevant business licenses. *Id.* § 12-6C-09.1(D)(3).

D. This Litigation.

AbbVie, Novartis, and PhRMA each filed suit in May and June, 2024, challenging H.B. 1056's constitutionality on several grounds and separately moving for a preliminary injunction. The district court consolidated those challenges.

Below, Appellants advanced a series of related but distinct theories. All Appellants argued that H.B. 1056 is field and conflict preempted by the federal 340B Program. AbbVie additionally argued that H.B. 1056 effectuates an unconstitutional taking by compelling AbbVie to transfer its drugs at significant discounts to private, for-profit pharmacies, rather than for a "public use." Finally, Novartis and PhRMA argued that H.B. 1056 unconstitutionally regulates wholly out of state transactions.

In opposition, the State adopted a series of conflicting positions about the law's basic meaning. At first, the Attorney General construed the law as a pricing regulation, explaining that a manufacturer violates H.B. 1056 whenever it fails to "honor[] the price … that's set forth in the 340B program." JA252. Later, the State switched gears and claimed that H.B. 1056 does not implicate pricing at all and instead regulates "delivery and delivery alone." JA841. But the Attorney General

undermined that new position by suggesting that H.B. 1056 does not reach conduct occurring "after purchase by a covered entity." Defs.' Memo ISO MTD (No. 24-1557, ECF 50-1) at 11. Delivery, of course, necessarily occurs after purchase. The confusion emanating from the State's evolving views is so obvious that the district court asked the Attorney General: "Do you appreciate that your colleague said something different the last time they were here?" JA480.

Nonetheless, on September 4, the district court delivered an oral ruling denying preliminary injunctive relief.[3] That ruling relied on several mistaken conclusions.

First, the district court concluded that H.B. 1056 merely regulates the "delivery" of drugs to contract pharmacies. JA882. But the defining feature of H.B. 1056 is *price*; the statute mandates that such deliveries occur at a federally specified discounted price—and requires that price when Congress has chosen not to. *See* H.B. 1056, § 12-6C-09.1(A)(4)(I)(2). The court then rejected Appellants' preemption arguments because, in its view, the federal 340B Program leaves sufficient room for Maryland to

[3] On September 5, the district court issued a written order, incorporating by reference its oral ruling. JA921-922.

"supplement" the federal scheme with "delivery" provisions. JA882. The court also concluded that the Maryland law's multiple state enforcement mechanisms do not impermissibly impinge on the exclusive federal enforcement scheme. JA886-887. Each of these conclusions is squarely in conflict with a recent decision of another district court in this circuit that preliminarily enjoined a substantially similar West Virginia law. *See Morrisey*, 2024 WL 5147643, at *7-12.

Second, the district court rejected AbbVie's takings claim on the ground that "[n]o taking occurs where a person or entity voluntarily participates" in the program at issue. JA874. The court concluded that because AbbVie "voluntarily" participates in certain federal programs, H.B. 1056 must be voluntary. JA876. The court also concluded that H.B. 1056 is not a regulatory taking. JA876-877. In its view, H.B. 1056 is insufficiently onerous (despite the multimillion dollar burdens it imposes), was foreseeable (even though H.B. 1056 imposes obligations on manufacturers that have never before existed in the 340B Program), and is aimed at promoting the public welfare (despite the record evidence that the arbitrage profits flow to the pharmacies themselves rather than patients). JA876-877.

The district court next concluded that even if H.B. 1056 effects a private taking, that taking serves a "public purpose" under the Fifth Amendment. JA877-878. Rather than discuss the evidence in the record or the particulars of Maryland's law, the district court simply emphasized that "public purpose" should be "conceived broadly" and that "legislative judgments" should receive "deference." JA877-878. The court then suggested that coercing AbbVie to provide its drugs at 340B prices to for-profit pharmacies would "protect the continued operation of providers that count as covered entities" and thus serves "a cognizable public purpose." JA878.

Third, turning to H.B. 1056's extraterritorial effect, the court concluded that H.B. 1056 "does not in itself set requirements for the terms of out-of-state sales." JA892. In holding so, the court accepted the State's atextual reading of H.B. 1056 that limits its applications to covered entities located in Maryland. JA892. It also appeared to rely on the State's proffered (though inconsistent) distinction to hold that H.B. 1056 impacted delivery, not pricing. JA893.

Finally, the district court ruled that the equities disfavored injunctive relief. The court assumed—without acknowledging

Appellants' contrary evidence—that the "implementation of H.B. 1056 would tend to increase the accessibility of 340B drugs to disadvantaged patients." JA896. The court did not explain how requiring manufacturers to provide 340B-priced drugs to for-profit pharmacies, who admit they do not pass on those discounted prices, serves patients or the broader public. *See* JA684, JA692-693; JA433.

Appellants promptly appealed.

SUMMARY OF THE ARGUMENT

The district court erroneously denied Appellants' motions to preliminarily enjoin H.B. 1056. Appellants are likely to succeed on the merits because the law offends the Constitution in multiple separate ways.

First, H.B. 1056 offends the Supremacy Clause because it thrusts Maryland into the middle of a complex and unified federal healthcare regime and meddles with the substantive rules and enforcement mechanisms that Congress created to govern it. H.B. 1056 also improperly conflicts with Congress's purposes: It vastly expands the scope of manufacturers' obligations (including by mandating the federal ceiling price under terms and conditions not required under federal law), thus skewing the balance Congress struck, and upending the exclusive enforcement regime Congress designed. *See Morrisey*, 2024 WL 5147643, at *10-11.

Second, H.B. 1056 works a physical taking because it coerces manufacturers to transfer their drugs to both covered entities and for-profit commercial pharmacies, against their will, under conditions Congress has not prescribed in the 340B Program. A manufacturer's

conscription into Maryland's law is not rendered voluntary by virtue of that manufacturer's participation in federal healthcare programs. Neither does H.B. 1056 accurately aim at any public use or public purpose, as the Fifth Amendment requires. Rather, evidence in the record demonstrates that the law will line the pockets of large, for-profit corporations. And even if there is no physical taking here, H.B. 1056 constitutes an impermissible regulatory taking.

Third, H.B. 1056 unlawfully regulates conduct occurring wholly outside of Maryland's borders. States may not directly regulate conduct that takes place wholly in another state. Yet, the Act purports to do just that. H.B. 1056 requires drug manufacturers to provide 340B-priced drugs to out-of-state pharmacies—it contains no geographic limitation cabining the scope of which pharmacies are covered by the Act. That directly governs conduct occurring wholly outside of the state.

Appellants will suffer irreparable constitutional and financial harms if forced to comply with H.B. 1056. Nor can the public interest be disserved by enjoining H.B. 1056; an unconstitutional law is never in the interest of the State or the public. The order below should be reversed.

STANDARD OF REVIEW

This Court reviews a district court's preliminary injunction decision for an abuse of discretion—but legal conclusions are reviewed de novo. *dmarcian, Inc. v. dmarcian Eur. BV*, 60 F.4th 119, 138 (4th Cir. 2023). Appellants are entitled to a preliminary injunction if they establish that (1) they are likely to succeed on the merits of their claims, (2) they are likely to suffer irreparable harm in the absence of preliminary relief, (3) the balance of equities tips in their favor, and (4) the public interest favors an injunction. *Id.* Because the State is the opposing party, factors three and four merge. *Miranda v. Garland*, 34 F.4th 338, 365 (4th Cir. 2022).

ARGUMENT

I. APPELLANTS' PREEMPTION CLAIMS ARE LIKELY TO SUCCEED ON THE MERITS.

Under the Constitution's Supremacy Clause, federal law is "the supreme law of the Land." U.S. Const., art. VI. And because federal law is supreme, Congress must be left to exercise its constitutional power unencumbered by the states. *McCulloch v. Maryland*, 17 U.S. 316, 436 (1819). Federal law thus preempts any state law that intrudes on an exclusively federal field or otherwise obstructs Congress's purposes. *See,*

e.g., *PPL EnergyPlus, LLC v. Nazarian*, 753 F.3d 467, 474, 478 (4th Cir. 2014). Appellants are likely to succeed in showing that H.B. 1056 is preempted under both field and conflict theories.

A. The Federal 340B Program Preempts the Field.

Maryland's law is field preempted. No state can regulate conduct "in a field that Congress … has determined must be regulated by its exclusive governance." *Arizona v. United States*, 567 U.S. 387, 399 (2012). Intent to displace state law in a field is evident in a "framework of regulation so pervasive" that "Congress left no room for the States to supplement it," or a legislative program concerning a "federal interest" so "dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Id.* (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

1. Congress Created a Comprehensive and Exclusively Federal Scheme.

In 340B, Congress created a comprehensive federal scheme for delivering a unique federal benefit to certain entities. The Program is an exclusive and closed system. And it is integrated within the federal government's broader healthcare framework. 340B is entirely a product of, and remains controlled by, federal law.

340B obligates participating pharmaceutical manufacturers to offer drugs to covered entities at the statute's ceiling price and provide that ceiling price should covered entities accept the offer made. 42 U.S.C. § 256b(a)(1). Congress and HHS have implemented that obligation through a detailed set of statutory provisions, rules, and guidance documents. Together those rules incentivize manufacturers' participation in 340B without becoming so onerous that manufacturers are motivated to withdraw from both 340B and other federal programs. And unlike Medicaid, which expressly invites states to participate in administering the federal program, nowhere does Section 340B authorize supplemental state regulations.

The Program's substantive rules specify what drugs are covered by the Program, *id.* § 256b(b)(2), the prices manufacturers must offer, *id.* § 256b(a)(1)-(2), the specific types of entities to whom manufacturers must make the offer, *id.* § 256b(a)(4), and the legal requirements that attach to covered entities—including prohibitions against duplicate discounting and diversion, and the obligation to permit audits, *id.* § 256b(a)(5)(A)-(C). Thus, while obligating manufacturers to offer specific drugs at specific prices to enumerated covered entities, the

Program also limits manufacturers' obligations by requiring them to make only a "bona fide" offer—thus reserving for them the freedom to impose reasonable terms. Further, the Program strictly proscribes potential abuse by covered entities. These limits reflect the balance Congress struck when enacting the 340B Program.

Congress and HHS have also created a comprehensive and exclusive remedial scheme for 340B. Congress granted the federal government exclusive authority to monitor Program compliance, with review by the federal courts, and provided it with compliance mechanisms such as civil monetary penalties and expulsion from the Program. *See id.* § 256b(d). Congress also instructed HHS to create an administrative dispute resolution process for disputes between covered entities and manufacturers regarding diversion, duplicate discounting, and overcharges. *Id.* § 256b(d)(3). HHS followed those instructions in April 2024 and fashioned a dispute resolution process that is now live and accepting claims. 89 Fed. Reg. 28643 (Apr. 19, 2024).

In addition, 340B rights and obligations constitute just a part of an integrated whole. The Program is one component of the federal government's multifaceted healthcare regime, with each program

intertwined with the others. Given the programs' interdependence, "an adjudication of rights under one program must proceed with an eye towards any implications for the other." *Astra USA, Inc. v. Santa Clara County, Cal.*, 563 U.S. 110, 114, 120 (2011). That is why the *Astra* Court concluded that private suits by 340B entities to enforce the Program's requirements would "undermine the agency's efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Id.* at 120.

Although *Astra* did not involve a preemption claim, *Astra* "evoked the legal concepts underlying federal preemption." *Bauer v. Elrich*, 8 F.4th 291, 306 (4th Cir. 2021) (Quattlebaum, J., dissenting).[4] As the

[4] The *Astra* Court undertook the same type of analysis appropriate for field preemption, concluding uniform national standards and enforcement are required. *Compare Astra*, 563 U.S. at 120 (need for uniformity), *with N.L.R.B. v. Nash-Finch Co.*, 404 U.S. 138, 144 (1971) (need for uniform standards and danger that state standards could produce conflict). The Court also recognized the necessity for centralized enforcement to balance vital federal interests. *Compare Astra*, 563 U.S. at 119-121 (If "HHS [was] unable to hold the control rein, the risk of conflicting adjudications would be substantial."), *with Arizona*, 567 U.S. at 401-02 (state enforcement would diminish federal government's control), and *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 350 (2001) (recognizing need for agency to police fraud consistently with the Administration's objectives).

Astra Court explained, "Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered entities." 563 U.S. at 117; *see Morrisey*, 2024 WL 5147643, at *9-10 (recognizing *Astra*'s application in this context). "[S]preading the enforcement burden" to "potentially thousands of covered entities" is "hardly what Congress contemplated when it 'centralized enforcement [of the 340B Program] in the [federal] government.'" *Astra*, 563 U.S. at 114, 119-20 (citing federal government's amicus brief).

For the same reason, Congress surely did not invite an ad hoc and un-coordinated effort—driven by Maryland and other states—to change its exclusively federal administrative and enforcement scheme. *See Beneficial Nat. Bank v. Anderson*, 539 U.S. 1, 11 (2003). Congress left no room for states to interfere with its uniform 340B scheme or to impose additional state-law obligations as conditions of participation in federal healthcare programs. When Congress creates a "single integrated and all-embracing system" like the 340B Program, it preempts the field. *Arizona*, 567 U.S. at 400 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 74 (1941)).

2. Maryland's H.B. 1056 Encroaches On The Exclusively Federal Field.

H.B. 1056 intrudes into the federal field both as to manufacturers' obligations and exclusive federal administration and enforcement.

1. Maryland apparently disagrees with the scope of obligations Congress imposed and has decided to append its own requirements onto the federal Program. It cannot. "[T]he states can exercise no powers whatsoever, which exclusively spring out of the existence of the national government." *U.S. Term Limits, Inc. v. Thornton*, 514 U.S. 779, 802 (1995). Here, Maryland has invaded the federal field by enacting its own statute that effectively expands the list of entities eligible for 340B pricing (or, at a minimum, upending the obligations Congress imposes and skewing the balance it struck), and subjecting manufacturers to a plethora of enforcement actions and onerous restrictions and penalties not contemplated by Congress that will disincentivize manufacturer participation.

This is literally the oldest preemption problem in the book. Like the Maryland law struck down in *McCulloch* attempting to tax only the Bank of the United States, *see* 17 U.S. at 435-36, H.B. 1056 applies only to 340B drugs. *See* H.B. 1056, §§ 12-6C-09.1(A)(2), (4) (pegging

operational terms to Section 340B). It regulates nothing except transactions undertaken pursuant to a federal program, governed by federal contracts between drug manufacturers and the United States. Indeed, H.B. 1056 could not exist but for the federal 340B Program. Maryland has no authority to directly regulate what Congress has made. *See Wis. Dep't of Indus., Lab. & Hum. Rels. v. Gould Inc.*, 475 U.S. 282, 288-89 (1986).

Even if Maryland thought that its scheme is complimentary of Congress's work, the Supreme Court's *Arizona* decision illustrates that such a defense falls flat. There, the Court found preempted a state law that made it a misdemeanor to willfully fail to "complete or carry an alien registration document" in violation of federal law. 567 U.S. at 400. In that way, the state added a "state-law penalty for conduct proscribed by federal law." *Id.* In finding the state provision preempted, the Court explained that "federal statutory directives provide a full set of standards governing alien registration, including punishment for noncompliance," which Congress designed to be a "harmonious whole." *Id.* at 401. "Where Congress occupies an entire field, as it has in the field of alien registration, even complementary state regulation is impermissible.

Field preemption reflects a congressional decision to foreclose any state regulation in the area, even if it is parallel to federal standards." *Id.*

Arizona's logic applies here. In fact, Maryland's H.B. 1056 is even more intrusive than the *Arizona* statute because it substantively *expands* obligations under a federal program and adds stiff state-law penalties for violations. H.B. 1056 obligates manufacturers participating in the 340B Program to provide their drugs at heavily discounted prices to a broader array of entities than federal law requires and under circumstances where federal law does not. H.B. 1056, § 12-6C-09.1(C)(1). And it imposes its own set of penalties—including criminal sanctions—to punish violators. *Id.* § 12-6C-09.1(D). That is not constitutional. The Supreme Court has explained that Congress intended the 340B Program to be a harmonious whole, enforced only by HHS. *Astra*, 563 U.S. at 120. Congress has occupied the field such that even purported complementary state regulation is impermissible.

In reaching the opposite conclusion, the district court emphasized Section 340B's purported "silence" about manufacturers' obligations concerning contract pharmacies. That was an error. Both the Third Circuit and D.C. Circuit have concluded the 340B Program "preserve[d]"

manufacturers' ability to limit the use of contract pharmacies through their "bona fide" offers. *See Novartis*, 102 F.4th at 460-64; *Sanofi*, 58 F.4th at 704-05. Congress's choice to omit such an obligation was not an invitation for states to impose their own.

Crucially, 340B prescribes conditions for participation in other federal programs—so what is *not* required is just as important as what *is* required. *See Novartis*, 102 F.4th at 460. That is, the 340B Program is an ostensibly voluntary scheme where manufacturers agree to a specific set of obligations in exchange for the opportunity to participate in Medicaid and other programs. By obliging those manufacturers to provide 340B-priced drugs to unlimited contract pharmacies, H.B. 1056 changes the terms of Congress's deal.

Finally, Maryland attempts to skirt around this problem altogether by pretending that H.B. 1056 says nothing about 340B drug pricing or eligibility. It claims that H.B. 1056 merely regulates the "delivery" of drugs that covered entities have already purchased. The district court largely adopted that framing, but this Court should not. *See Morrisey*, 2024 WL 5147643, at *8-9 (rejecting "delivery" characterization and stating it is "about delivery *at a given price*, not delivery *per se*").

By its own terms, H.B. 1056 regulates *who* can acquire drugs at the federal ceiling price. After defining "340B drug" by reference to that drug's discounted price, the statute forbids manufacturers from limiting "the *acquisition of a 340B drug* by, or delivery of a 340B drug to, a [contract] pharmacy." H.B. 1056, §§ 12-6C-09.1(A)(4), (C)(1) (emphasis added). Under basic principles of statutory interpretation, courts may not read the word "acquisition" out of the statute or render it superfluous. *See United States v. Young*, 989 F.3d 253, 259 (4th Cir. 2021). So, H.B. 1056's reach necessarily extends beyond delivery requirements; it forces manufacturers to allow contract pharmacies to acquire their drugs at discounted prices by dictating the terms of the manufacturers' 340B offer. *See Morrisey*, 2024 WL 5147643, at *8 ("The question is only about what price the pharmacy and the covered entity will pay the manufacturer for the replenished drug upon distribution of the 340B Program eligible one.").

A hypothetical illustrates the point. A manufacturer would face penalties under the law if it offered unlimited quantities of its drugs for purchase to contract pharmacies, delivered direct to the pharmacy, but requested payment *above* the 340B ceiling price. Yet a manufacturer

would not face such liability if its offer included pricing at or below the ceiling price. In other words, the statute regulates *pricing* and *eligibility*, not methods of distribution. Imagine, by contrast, a state law requiring delivery of drugs by temperature-controlled trucks, or a law that required all drugs be shipped in red boxes for ease of demarcation. *Those* would be delivery regulations. H.B. 1056 is not.

Further, H.B. 1056 explicitly extends to drugs that *have not yet been purchased* by a covered entity and therefore do not even qualify for 340B pricing. It specifies that the term "340B drug" includes drugs "that *would have* been purchased but for" manufacturers' policies limiting contract-pharmacy access to discounted prices. H.B. 1056, § 12-6C-09.1(A)(4)(II) (emphasis added). In the federal scheme, a covered entity can only "purchase" a 340B drug at the 340B price if it accepts a manufacturer's "offer" (which can include restrictions on contract pharmacy use)—if it does not, the manufacturer is not required to provide the 340B price. 42 U.S.C. § 256b(a)(1); *Novartis*, 102 F.4th 460. Accordingly, Maryland's statute is not limited to back-end delivery logistics for covered entities' purchased drugs. It attaches requirements to the very "offer" at the heart of the federal 340B Program and requires manufacturers to provide the

340B price where there is no qualifying 340B "purchase." *See* 42 U.S.C. § 256b(a)(1).

On-the-ground practice also confirms that H.B. 1056 regulates pricing, not delivery. Most contract pharmacies operate under the "replenishment model," meaning they dispense all drugs—340B or not—from the same undifferentiated inventory. *E.g.*, JA174-176 (¶¶ 6–12); JA215-218 (¶¶ 3–11); JA422-423; JA553-557; JA743. The only thing that changes for 340B drugs is the price paid on the back end for replenishment orders. *See* JA174-175 (¶ 7); JA216 (¶¶ 4–6); JA765-767 (¶8a–d). Indeed, no one disputes that manufacturers will—and indeed already do—*deliver* their drugs to any pharmacy that wants them, subject to other federal laws. Maryland's law targets the *price* that manufacturers demand for those deliveries. At oral argument, the Maryland Attorney General's representative explained why a full-price delivery would violate H.B. 1056: "The violation would be the refusal to deliver at the 340B *price* if it's a 340B drug." JA274 (emphasis added).

Applying similar logic, a federal district court in West Virginia recently refuted the State's "delivery" characterization. In particular, the court observed that these state laws fundamentally regulate "price, not

delivery." *Morrisey*, 2024 WL 5147643, at *8-9. Manufacturers, the court observed, risk violating such laws "not by withholding drugs from contract pharmacies, but by refusing the 340B discount when delivering [their] drugs to those pharmacies." *Id.* (citation omitted). "The question is only about what price the pharmacy and the covered entity will pay the manufacturer for the replenished drug upon distribution of the 340B Program eligible one"—thus, the state law had everything to do with "delivery *at a given price*" and nothing to do with "delivery *per se*." *Id.*

At bottom, Maryland's "delivery" framing is a purely semantic exercise. But "[p]re-emption is not a matter of semantics" and states cannot "evade the pre-emptive force of federal law by resorting to creative statutory interpretation or description at odds with the statute's intended operation and effect." *Wos v. E.M.A.*, 568 U.S. 627, 636 (2013). "[A] proper [preemption] analysis requires consideration of what the state law in fact does, not how the litigant might choose to describe it." *Id.* at 637.

This Court's *PPL EnergyPlus* decision illustrates the appropriate way to handle Maryland's word games. *See* 753 F.3d at 476-77. *PPL EnergyPlus* concerned a Maryland policy that encouraged the

construction of a new power plant by guaranteeing a fixed revenue stream to the builder. *Id.* at 473. Other power-plant companies claimed that Maryland's policy intruded on the federal government's scheme regulating interstate energy markets. *Id.* at 474. Not so, assured Maryland. The federal scheme foreclosed rate-setting policies, it argued, but Maryland's policy was just an internal "supply-side subsidy" with no direct effect on "the terms of any transaction in the federal market." *Id.* at 476. This Court was not amused. Judge Wilkinson rejected Maryland's "attempt to evade preemption" with "mere formal distinctions," instead focusing on the policy's "functional results." *Id.* at 476-77 (internal quotation marks omitted); *see also Hughes v. Talen Energy Mktg., LLC*, 578 U.S. 150, 164-66 (2016) (affirming *PPL EnergyPlus* and endorsing reasoning).

Maryland is now reaching into the same bag of tricks. But notwithstanding the state's "delivery" fiction, H.B. 1056 "functionally" regulates the price at which contract pharmacies access manufacturers' drugs and requires manufacturers to provide the federal price where federal law does not. *See PPL EnergyPlus*, 753 F.3d at 476. It thus encroaches on the 340B field that federal law preempts, even if that field

is limited to "pricing" issues as Maryland claims. Since "[p]rice regulation is exclusively controlled by the federal statute, … state enforcement of it would necessarily intrude on the federal [340B] scheme." *Morrisey*, 2024 WL 5147643, at *10 (citation omitted).

2. H.B. 1056 also impermissibly sets up its own scheme of oversight and enforcement to penalize manufacturers for not supplying 340B-priced drugs to contract pharmacies. As *Astra* explained, 340B has a robust enforcement and remedial scheme, centralized within HHS. 563 U.S. at 113. Yet, H.B. 1056 grants Maryland authorities the ability to control 340B sales, which will (as the *Astra* Court predicted) create contradictory results. Maryland thus steals from the federal agency, superintended by federal courts, the authority to make exclusive discretionary judgments regarding enforcement and the limits of 340B's obligations and ultimately compromises the federal government's ability to balance the interests of 340B, Medicare, and Medicaid. *See id.* at 120.

And while the district court seemed to think that contract pharmacy issues are outside the scope of the exclusive federal enforcement mechanisms, the federal government *itself* has taken the position that adjudication of "overcharging," *i.e.*, a term for when a

manufacturer charges a covered entity more than the 340B price, encompasses disputes related to the use of contract pharmacies (the same topic covered by H.B. 1056). *See supra* §A.1; *see also* Gov't Reply Br. at 5, *Am. Hosp. Ass'n v. HHS*, No. 20-cv-08806 (N.D. Cal. Feb. 1, 2021) (ECF No. 82) ("The contract-pharmacy dispute must be resolved through ADR" and relying on *Astra*); 89 Fed. Reg. at 28649. In any event, even if manufacturers' policies do not fall within the overcharging bucket as covered entities previously asserted, the federal statute, in 42 U.S.C. § 256b(d)(1), provides for HHS's enforcement authority over both "overcharges *and other violations*," including any drug manufacturer's purported violations of the "shall offer" provision at Section 256b(a)(1). *Astra*, 563 U.S. at 121-22 (emphasis added). That is expressly what Maryland is trying to regulate here: the terms of a drug manufacturer's "offer" to sell 340B-priced drugs.

B. H.B. 1056 Conflicts With The Federal 340B Program.

For similar reasons, H.B. 1056 is conflict preempted because it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" in creating the 340B Program. *Arizona*, 567 U.S. at 399 (quoting *Hines*, 312 U.S. at 67); *see also PPL*

EnergyPlus, 753 F.3d at 478 (noting the "mutually reinforcing" nature of field and conflict preemption in some cases). H.B. 1056 conflicts with federal law by compelling Appellants to provide their drugs at the federal ceiling price to entities not enumerated in the federal statute and in circumstances not required by 340B (including where there is no qualifying federal purchase)—and then subjecting Appellants to a parallel and supplemental state enforcement scheme. Maryland's law thus expands Appellants' obligations under the Program, adds new civil and criminal penalties for noncompliance, and limits manufacturers' ability to utilize what was intended to be an exclusively federal enforcement regime.

1. H.B. 1056 Undermines Congress's Carefully Balanced Scheme By Expanding Manufacturers' Obligations Under The 340B Program.

H.B. 1056 conflicts with Section 340B because it expands manufacturers' obligations under the federal Program by compelling them to provide their drugs at discounted prices to contract pharmacies in circumstances not required by Congress. That imposition "upsets the balance struck" in the 340B Program, thereby creating an "obstacle to the federal plan of regulation and control." *Arizona*, 567 U.S. at 403.

In crafting Section 340B, Congress struck a careful balance between competing interests. It wanted to ensure that certain non-profit healthcare providers could access affordable drugs. But at the same time, it needed to incentivize drug manufacturers to participate in the 340B Program. Accordingly, Congress defined the Program's scope and obligations broadly enough to meet its drug-affordability goals, but narrowly enough to prevent overburdened manufacturers from withdrawing from the Program altogether.

As part of that balance, Congress opted *not* to include any affirmative obligations concerning contract pharmacies. *See Sanofi*, 58 F.4th at 704; *Novartis*, 102 F.4th at 464. That omission was not a "gap" left for states to fill on their own. It was an intentional policy choice that reflects Congress's considered judgment.

Several textual cues bear that out. First, Section 340B specifically enumerates the entities entitled to 340B pricing but does not include contract pharmacies. "It is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication." *AstraZeneca*, 543 F. Supp. 3d at 60. Second, Congress "expressly

contemplates drug makers selling discounted drugs through contract pharmacies" in a different drug-pricing statute. *Sanofi*, 58 F.4th at 704-05 (citing 38 U.S.C. § 8126). It is safe to presume that Congress acted "intentionally" when it left such language out of 340B. *Id.*[5]

In fact, Section 340B's legislative history proves the point. Congress *rejected* a bill that would have required 340B-priced drugs to be distributed "under a contract entered into for on-site pharmacy services." S. Rep. No. 102-259 § 2141(b) (1992). Congress made the deliberate decision to omit that language. In other words, Congress specifically chose *not* to require manufacturers to provide 340B-priced drugs to contract pharmacies. And that decision reflects Congress's "considered judgment" that such an obligation "would be inconsistent with federal policy and objectives." *Arizona*, 567 U.S. at 405.

Second, Section 340B requires only that a manufacturer "offer" certain drugs to covered entities at the applicable ceiling price. 42 U.S.C.

[5] This is underscored by Congress barring covered entities from "resell[ing] or otherwise transfer[ring]" 340B-priced drugs "to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). This diversion prohibition reinforces Congress's intent to limit manufacturers' subsidies.

§ 256b(a)(1). As both the D.C. and Third Circuit have held, that offer can include limitations on the use of contract pharmacies, including claims data requirements. *See Sanofi*, 58 F.4th at 704; *Novartis*, 102 F.4th at 464. A covered entity must then "assent" to those terms or reject the offer. *Novartis*, 102 F.4th at 460. In the latter scenario, there is no 340B purchase to which the ceiling price applies. *Id.*; 42 U.S.C. § 256b(a)(1).

Maryland now undermines Congress's judgment by imposing its own contract-pharmacy obligation on manufacturers participating in the 340B Program, setting up a direct conflict. Whereas Congress chose to impose a pricing obligation only where there was a qualifying purchase, 42 U.S.C. § 256(a)(1), Maryland has now stepped in and explicitly required the federal price even where no such purchase—following acceptance of a manufacturer offer—has occurred. H.B. 1056, §§ 12-6C-09.1(A)(4)(II), (C)(1) (mandating manufacturers provide 340B-priced drugs where they "would have been purchased but for" a manufacturer's reasonable, federally permissible conditions on their offer). The only way that H.B. 1056 can mandate that manufacturers provide the federal ceiling price is by running afoul of 340B's limitation that federal pricing applies where there is a qualifying "purchase." That both sets up a direct

conflict and dramatically enlarges the Program's burdens on participants, "skew[ing]" the finely-wrought balance that Congress struck. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001).

The district court shrugged that problem aside, reasoning that "the Maryland statute assists in fulfilling the purpose of 340B." JA886. By the court's logic, conflict does not exist where a state law seeks one of the same general substantive ends—like discounted drug prices—as a federal regime. That is incorrect.

The Supreme Court soundly rejected such logic in *Arizona*. Although H.B. 1056 "attempts to achieve one of the same goals as federal law," it "involves a conflict in the method of enforcement." And "a conflict in technique can be fully as disruptive to the system Congress erected as conflict in overt policy." *Arizona*, 567 U.S. at 406 (quoting *Motor Coach Emps. v. Lockridge*, 403 U.S. 274 (1971)); *accord PPL EnergyPlus*, 753 F.3d at 478 (striking down a Maryland policy for "interfer[ing] with the method by which the federal statute was designed to reach its goals" (quoting *Public Utility Dist. No. 1 of Grays Harbor Cnty. Wash v. IDACORP Inc.*, 379 F.3d 641, 650 (9th Cir. 2004)). Thus, Maryland

cannot "assist" Section 340B by unilaterally broadening the federal statute's scope and expanding its obligations.

More fundamentally, Section 340B aims to incentivize manufacturers to participate without becoming so exploitive as to encourage their withdrawal. As such, the statute's "purposes" include not just the benefits it creates for covered entities, but also the limitations Congress set on the Program's scope and the protections for manufacturers against abuse. *See Novartis Pharms. Corp. v. Espinosa*, 2021 WL 5161783, at *7 (D.D.C. Nov. 5, 2021) (rejecting suggestion that legal requirements of unlimited contract pharmacies is consistent with 340B's purpose because "no legislation pursues its purposes at all costs" and "Section 340B is no exception"); *see also Rapanos v. United States*, 547 U.S. 715, 752 (2006) ("[T]extual *limitations* upon a law's scope are no less a part of its 'purpose' than its substantive authorizations." (emphasis added)). Indeed, as the district court in West Virginia observed, the 340B Program's "twin federal purposes" include "providing discounts to covered entities only *and* prohibiting fraud through duplicate discounts." *Morrisey*, 2024 WL 5147643, at *6.

H.B. 1056 impedes that purpose by substituting Maryland's preferred methods for Congress's.

2. H.B. 1056 Thwarts Congress's Intent To Vest Exclusive Authority For Enforcing Section 340B In The Federal Government.

Maryland's law also clashes with Congress's carefully calibrated enforcement scheme in two ways. First, H.B. 1056 empowers the Maryland Attorney General and Board of Pharmacy to impose various state sanctions—including civil and criminal penalties—on manufacturers who fail to provide 340B-priced drugs to contract pharmacies. That state enforcement regime will "inevitability conflict" with the federal government's ability to police 340B compliance "consistently with [its] judgment and objectives." *Buckman*, 531 U.S. at 350. Second, H.B. 1056 erects a serious barrier to accessing the federal enforcement scheme.

a. H.B. 1056's Additional Enforcement Scheme Wrests Significant Power From The Federal Government.

Section 340B's compliance scheme reflects several of Congress's considered judgments. First, Congress made the federal government the sole and exclusive enforcement arm of the 340B Program, with review by

the federal courts. *See Astra*, 563 U.S. at 120. In addition, Congress specifically delineated which tools the agency could use to ensure that participating manufacturers comply with the Program's requirements. 42 U.S.C. §§ 256b(d)(l)(B)(v), (d)(3). Accordingly, HHS created ADR to adjudicate pricing and other specified disputes between covered entities and manufacturers. *Id.* § 256b(d)(3)(A); 42 C.F.R. § 10.21(a); *see Cap. Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 698-99 (1984) (clarifying that federal regulations have the same preemptive force as federal statutes).

Maryland now undermines those judgments by authorizing its own officers to police manufacturers' participation in the 340B Program. *See Morrisey*, 2024 WL 5147643, at *12 (holding it "should be apparent" that enforcement of state statute "cut[s] against the Supreme Court's holding in *Astra*"). Those state officers can bring new types of sanctions—including criminal penalties—that Congress did not empower even HHS to bring. H.B. 1056, § 12-6C-09.1(D); Md. Code Ann., Com. Law §§ 13-406, -410 to -411; *see Arizona*, 567 U.S. at 404-05 (finding conflict where a state imposed misdemeanor penalties for conduct that the federal government regulated with only civil consequences). So, if Appellants refuse to provide 340B pricing on drugs that they deliver to contract

pharmacies, they now will face sanctions (that Congress did not want) in a state-court tribunal (that Congress did not empower). "'Conflict is imminent' when 'two separate remedies are brought to bear on the same activity.'" *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 380 (2000) (quoting *Wis. Dep't of Indus.*, 475 U.S. at 286).

The district court was wrong to find that the federal and state enforcement schemes operate in wholly different spheres. JA886-887. Indeed, a state decisionmaker will need to resolve multiple complex questions of federal law in determining whether a manufacturer violated H.B. 1056. H.B. 1056 prohibits a manufacturer from limiting the acquisition of "a 340B drug" by a contract pharmacy authorized by "a covered entity" to receive it. H.B. 1056, § 12-6C-09.1(C)(1). Thus, Maryland, in enforcing the law, would need to determine: (1) whether the denied prescriptions and drugs were actually eligible for 340B pricing; (2) whether the manufacturer provided the 340B price; (3) whether there has been diversion or duplicate discounting (which includes determining whether a specific drug was distributed to a covered entity's "patient"); and (4) whether a covered entity is (and remains) a covered entity. Answering these questions would require Maryland to grapple with

questions regarding how 340B is to be interpreted and applied, creating the "substantial" "risk of conflicting adjudications" that drove the decision in *Astra*. 563 U.S. at 120. It was that very same risk that led the West Virginia court, citing *Astra*, to find conflict preemption: "If private attempts to enforce the 340B Program go against 'what Congress contemplated when it "centralized enforcement in the government,"' then so too would public attempts," like Maryland's, "to enforce it." *Morrisey*, 2024 WL 5147643, at *10; *see also id.* at *11 (explaining that under the parallel enforcement scheme erected by state law "it is likely that a drug manufacturer could both restrict distribution at the 340B price because of diversion concerns and be subject to sanction under [state law]").

b. H.B. 1056 Creates A Significant Obstacle To Using The Federal Enforcement Mechanism.

H.B. 1056 also severely limits manufacturers' ability to gather claims data critical to use the audit and ADR processes and determine if diversion, duplicate discounting (requesting a rebate under Medicaid for a 340B drug), and other abuses are occurring. The district court inexplicably did not address this issue, which at a minimum warrants

vacatur (if not outright reversal). *See Brewster of Lynchburg, Inc. v. Dial Corp.*, 33 F.3d 355, 366-67 (4th Cir. 1994).[6]

H.B. 1056 prohibits manufacturers from "limit[ing] the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with" a covered entity. H.B. 1056, § 12-6C-09.1(C)(1). To the extent H.B. 1056's plain language prohibits manufacturers from requiring claims data regarding 340B-priced drugs, that data is critical to access federal ADR. To use ADR, manufacturers must first audit a covered entity. *See* 42 U.S.C. §§ 256b(a)(5)(C), (d)(3). And manufacturers are only permitted to conduct an audit where they "ha[ve] documentation which indicates there is reasonable cause." 61 Fed. Reg. 65406, 65409 (Dec. 12, 1996); 89 Fed. Reg. at 28644. "Reasonable cause" is defined to mean "that a reasonable person could believe that a covered entity may

[6] Below, Maryland stated that "because HB 1056 provides that it shall not be construed to conflict with applicable federal law …, it could not be construed to deny a manufacturer any information it is entitled to under federal law." Defs.' Combined MTD & Opp'n to Mot. for PI at 29, No. 24-1631 (ECF 19-1). However, it never directly acknowledged that claims data policies were lawful under H.B. 1056 or that H.B. 1056 would be conflict preempted to the extent it barred such policies. And, in any event, the saving clause cannot bear the weight the district court placed upon it. *Morrisey*, 2024 WL 5147643, at *11.

have violated" the prohibitions on transfer or sale, or on duplicate discounting. 61 Fed. Reg. at 65409. Ability to collect claims data thus directly and significantly affects manufacturers' ability to establish reasonable cause and access the federal audit and ADR processes. *Espinosa*, 2021 WL 5161783, at *8 (holding that, under federal law, manufacturers are permitted to require certain types of data as a precondition of their "offer" of 340B-priced drugs); *id.* (recognizing claims data conditions enable manufacturers "to better utilize the anti-fraud audit and ADR procedures"); *Novartis*, 102 F.4th at 464 (affirming holding).

As another court in this Circuit recognized in holding a claims data bar preempted, 340B has twin purposes, "providing discounts to covered entities only *and* prohibiting fraud[.]" *Morrisey*, 2024 WL 5147643, at *6. But "[b]y restricting the very method by which data collection is made, [a claims data bar] frustrates drug manufacturers' ability to take the initial steps necessary to start the very audit process required to access the alternative dispute resolution system." *Id.* That stands as an "obstacle to achieving the federal objective of preventing fraud in the 340B Program," rendering it preempted. *Id.* at *7.

Here, as there, H.B. 1056 would prohibit the collection of claims data and create a significant obstacle to using the audit and ADR processes. H.B. 1056 is incompatible with Section 340B.

C. No Presumption Against Preemption Applies to H.B. 1056.

The district court avoided the conclusion H.B. 1056 was preempted by leaning on the presumption that Congress does not intend to preempt state or local regulation of fields traditionally occupied by states. JA883. But that presumption does not apply to H.B. 1056.

First, the Supreme Court has refused to extend the presumption against preemption to state laws that explicitly depend on a federal statute—that is, when the regulated subject matter "is inherently federal in character" because it "originates from, is governed by, and terminates according to federal law." *Buckman*, 531 U.S. at 347-48. *Buckman* concerned state tort claims alleging that medical device manufacturers' misleading statements to a federal agency caused plaintiffs to suffer injuries from defective devices. But because the manufacturers' dealings with the agency "were prompted by" and "dictated by" a federal statute, no presumption against preemption applied. *Id.* Likewise, H.B. 1056 exclusively regulates conduct "prompted by" and "dictated by" Section

340B. It could not exist without the federal 340B Program, which imposes obligations that manufacturers accept (on an ostensibly voluntary basis) in exchange for other federal benefits. *Cf. Boyle v. United Techs. Corp.*, 487 U.S. 500, 504 (1988) (holding that state tort claims implicated a "uniquely federal" interest because they involved liability arising from a manufacturer's contract with the federal government).

Second, H.B. 1056 does not implicate states' traditional police powers. The question is not whether Maryland may regulate public health or the practice of pharmacy—H.B. 1056 regulates neither. It does not govern, for example, the safe handling of drugs or the way pharmacists compound prescriptions. It does not even regulate the prices paid by consumers at the drug store. Instead, it barges into the federal field of 340B pricing and eligibility by requiring manufacturers to provide their products to commercial pharmacies at legislatively set prices—in circumstances where the federal statute imposes no such requirement. 340B and its requirements are "hardly 'a field which the States have traditionally occupied.'" *Buckman*, 531 U.S. at 347 (quoting *Rice*, 331 U.S. at 230).

Maryland cannot merely point to the words "drug" and "pharmacy" to label H.B. 1056 a "health and safety" regulation. *Buckman* itself rejected such an approach: Even though the preempted tort claims involved physical injuries caused by defective medical devices, they did *not* implicate "the historic primacy of state regulation of matters of health and safety." Rather, they policed "fraud against federal agencies"—something outside the states' traditional domain. *Id.* at 347-48.

H.B. 1056 is not entitled to a presumption against preemption. And because the statute intrudes on an exclusively federal field—340B drug pricing and eligibility—and conflicts with 340B, it is preempted.

D. The Eighth Circuit's *McClain* Decision Does Not Control This Case.

In rejecting Appellants' preemption claims, the district court relied heavily on the Eighth Circuit's *Pharmaceutical Research & Manufacturers of America v. McClain* decision. 95 F.4th 1136 (8th Cir. 2024); *see* JA880-883, JA886. That reliance was misguided. Although the Eighth Circuit upheld an Arkansas law similar to H.B. 1056, its decision does not control here: *McClain* rests on several baseless premises. As such, it is unpersuasive and inapplicable to the present dispute.

First, *McClain* assumed that the Arkansas statute merely regulated drug "delivery" and the "practice of pharmacy"—areas traditionally left to state regulation. *McClain*, 95 F.4th at 1143-44, 1145. That is not true of H.B. 1056.

Maryland's law does not regulate traditional state areas but instead regulates drug *pricing* and *eligibility* under a purely *federal* regime. The law instructs that manufacturers may not prohibit the "acquisition" of *340B-priced* drugs *by* commercial pharmacies. H.B. 1056, § 12-6C-09.1(C)(1); *see id.* § 12-6C-09.1(A)(4)(I)(2) (defining the drugs by reference to the federal 340B price). Put simply, Maryland's law has everything to do with *whether* Appellants will provide their drugs at 340B prices and *to whom*, but nothing to do with *how*. *See supra* at §I.A-B.

The district court in West Virginia took the same view: it concluded that West Virginia's substantially similar state law regulates "price, not delivery"—in other words, "delivery *at a given price*, not delivery *per se*." *See Morrisey*, 2024 WL 5147643, at *8. On that basis, the court declined to accept *McClain*'s "rather brief rejection of an obstacle preemption argument." *Id.* at *11. And it further rejected the conclusion of another decision on which the court below relied—*AbbVie Inc. v. Fitch*, 2024 WL

3503965 (S.D. Miss. Jul. 22, 2024); JA881—because that court "rather summarily concluded that" the state law in issue "addresses delivery and Section 340B does not." *Morrisey*, 2024 WL 5147643, at *11.

Second, the Arkansas law at issue in *McClain* did not include the provision in Maryland's law that requires delivery of a 340B drug "that would have been purchased but for" a manufacturer's limit on the use of contract pharmacies in the federal 340B offer. H.B. 1056, §§ 12-6C-09.1(A)(4)(II), (C)(1). This operates directly on the 340B Program's scope and changes what drugs a covered entity may "purchase" at the 340B ceiling price, underscoring that H.B. 1056 substantively alters the 340B Program. *See supra* §I.A-B.

Third, *McClain* couched its holding, that the Arkansas statute did not introduce contract pharmacies into 340B's closed system, on its premise that covered entities—the only entities eligible for 340B discounts—retain title to 340B-priced drugs. *See* 95 F.4th at 1142, 1144. But that premise is faulty. The only evidence *McClain* cited in support was HRSA's 1996 prospective guidance describing how the 340B Program should work. *Id.* at 1142 (citing 61 Fed Reg. at 43550-52); *see Novartis*, 102 F.4th at 456-57 (explaining that the 1996 guidance sought

to "move the program forward" and noting that, in a later guidance document, "HRSA reiterated *its view* that each covered entity must maintain title to and responsibility for the drugs" (emphasis added)). That guidance does not establish that covered entities *actually* retain title.

Appellants' evidence demonstrates that covered entities do *not* retain title to 340B drugs. *See, e.g.*, JA556-557; JA174 (¶ 6); JA176 (¶¶ 9, 11); JA767 (¶ 8e–f); JA218 (¶ 11). When a contract pharmacy receives a 340B-priced drug, that drug is placed on the shelf where it becomes "neutral inventory." JA218 (¶ 11); JA216 (¶ 4). In other words, covered entities do not retain title: at the time of sale to a patient, a particular unit of drug is owned by the pharmacy itself. JA176 (¶ 11). Pharmacies admit they do not maintain physically segregated inventories for 340B and non-340B drugs. JA174 (¶ 6); JA176 (¶ 11). Representatives of covered entities agree. JA553-557.

Fourth, *McClain* (and the district court here) assumed that each contract pharmacy acts as an agent of a covered entity, and so does not become part of the 340B system. 95 F.4th at 1142; JA882. But that is not true. JA117 ¶¶ 14, 16. Agency relationships require the principal to

have "the right to control the conduct of his alleged agent." *Myrick v. Prime Ins. Syndicate, Inc.*, 395 F.3d 485, 491 (4th Cir. 2005). But covered entities rarely exercise that level of control over pharmacies, if at all. Rather, contract pharmacies often order 340B drugs from manufacturers themselves, using the covered entities' purchasing accounts, and sometimes even without the covered entities' knowledge. JA176 (¶ 12). And while *McClain* looked to HRSA's 1996 guidance, that guidance does not address what actually occurs on the ground.

Finally, *McClain* did not consider or address the issue of claims data. Only one court has squarely addressed this issue, and it concluded that a prohibition on the collection of claims data was preempted because it stood "as an obstacle to achieving the federal objective of preventing fraud in the 340B Program." *Morrisey*, 2024 WL 5147643, at *7.

II. ABBVIE'S TAKINGS CLAIM IS LIKELY TO SUCCEED ON THE MERITS.

H.B. 1056 effectuates an unconstitutional physical taking because it compels the transfer of AbbVie's property to other private parties that will sell the drugs at regular prices and retain the profit for themselves. That kind of conduct has *never* been allowed under the Fifth Amendment, which permits the taking of private property only for "public use." U.S.

Const. amend. V; *see also Calder v. Bull*, 3 U.S. 386, 388 (1798). No amount of compensation can cure the constitutional harm that is inflicted by a taking for private use.

The Supreme Court has articulated several principles that are relevant here and ought to guide this Court's consideration.

First, "[h]istory and precedent" should guide any Takings Clause analysis. *Tyler v. Hennepin Cnty.*, 598 U.S. 631, 639 (2023). Supreme Court precedents stretching from the Founding to the modern day have recognized that the Takings Clause cannot justify a forced transfer from one private party to another. *See, e.g.*, *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 543 (2005); *Calder*, 3 U.S. at 388.

Second, the takings analysis should be fitted to the "particular circumstances" of this case, rather than governed by "blanket exclusionary rules." *Ark. Game & Fish Comm'n v. United States*, 568 U.S. 23, 37 (2012). That means vague appeals to the State's "police power" are insufficient to justify a taking because if "the uses of private property were subject to unbridled, uncompensated qualification under the police power, 'the natural tendency of human nature would be to extend the qualification more and more until at last private property

disappeared.'" *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1014 (1992) (quoting *Penn. Coal Co. v. Mahon*, 260 U.S. 393, 416 (1922)).

Finally, "[t]he Takings Clause 'was designed to bar Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole.'" *Tyler*, 598 U.S. at 647 (quoting *Armstrong v. United States*, 364 U.S. 40, 49 (1960)). Indeed, the "Founders recognized that the protection of private property is indispensable to the promotion of individual freedom. As John Adams put it, 'property must be secured, or liberty cannot exist.'" *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 147 (2021) (quoting Discourses on Davila, in 6 Works of John Adams 280 (C. Adams ed. 1851)).

AbbVie is likely to succeed on its takings claim because H.B. 1056 effects a coercive, physical taking for private use. But even if this Court disagrees, AbbVie's takings claim is still likely to succeed because H.B. 1056 constitutes a regulatory taking.

A. H.B. 1056 Effectuates A Physical Taking.

H.B. 1056 works a physical taking that implicates the Takings Clause. Thus, it would be improper to apply the regulatory takings analysis here.

When the government acquires property for itself or a third party, it effects a "physical appropriation[]" that "constitute[s] the 'clearest sort of taking.'" *Id.* at 148 (quoting *Palazzolo v. Rhode Island*, 533 U.S. 606, 617 (2001)). On this, the Court has been clear: "Government action that physically appropriates property is no less a physical taking because it arises from a regulation." *Id.* at 149. The "essential question" when deciding whether a taking is physical or "regulatory" is "whether the government has physically taken property for itself or someone else—by whatever means—or has instead restricted a property owner's ability to use his own property." *Id.* Whenever a law "results in a physical appropriation of property, a *per se* taking has occurred." *Id.* H.B. 1056 achieves this sort of physical taking by compelling a transfer of AbbVie's property to private parties.

H.B. 1056's text confirms it compels the transfer of property. The Act instructs that a manufacturer "may not directly or indirectly deny,

restrict, prohibit, discriminate against, or otherwise limit the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with or otherwise authorized by a covered entity to receive 340B drugs on behalf of the covered entity." H.B. 1056, § 12-6C-09.1(C)(1). The ordinary meaning of "acquisition" is the "gaining of possession or control over something." Black's Law Dictionary (12th ed. 2024); *see also* Merriam-Webster Dictionary (defining "acquire" as "to come into possession or control of often by unspecified means"). So H.B. 1056, in plain English, prohibits AbbVie from preventing commercial pharmacies from taking possession of AbbVie's drugs at significantly discounted prices. That is a taking. *See Horne v. Dep't of Agric.*, 576 U.S. 350, 362 (2015) (explaining that the "actual taking of possession and control" is "a taking as clearly 'as if the [receiving party] held full title and ownership'" (quoting *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 431 (1982)); JA174, JA176, JA177 (¶¶ 6, 11, 14, 16). As the Supreme Court recently made clear, just as the "government commits a physical taking when it uses its power of eminent domain to formally condemn property," "[t]he same is true when the government physically takes

possession of property without acquiring title to it." *Cedar Point*, 594 U.S. at 147.[7]

Practice on the ground, too, confirms that H.B. 1056 will require a transfer of AbbVie's drugs at a particular price rather than, as the State and the district court believe, simply prescribing a method of delivery. If H.B. 1056 stands, contract pharmacies will place orders for discounted drugs and AbbVie will have no choice but to accept and fulfill those orders. JA176-177 (¶¶ 12–13). The pharmacies will then take title to the drugs, merge them with their general inventory, and dispense them to customers irrespective of whether those customers are patients of a covered entity. JA174, JA176, JA177 (¶¶ 6, 11, 14, 16). That will increase the volume of drugs given away at penny prices so that covered entities and contract pharmacies can resell them at retail prices and generate revenue. JA174 (¶ 6). Rules concerning "delivery" or "distribution" do not create massive revenue streams the State claims it is trying to protect—price fixing regimes do that.

[7] That the drugs H.B. 1056 targets are personal rather than real property is irrelevant to the takings analysis. *Horne*, 576 U.S. at 358.

For these reasons, the district court was incorrect to reject AbbVie's arguments on the ground that "the products at issue are transferred through sale to covered entities, not confiscation by the Government." JA876. First, Supreme Court precedent demonstrates that a taking is just as much a taking when the government takes property for itself as compared to when it takes property for a third party. *See Cedar Point Nursery*, 594 U.S. at 148. Second, the record reveals that the district court's conclusion is true only in the strictest sense. Sure enough, contract pharmacies leverage a covered entity's purchasing account to acquire drugs at significant discounts for themselves. But that the covered entity passively acts as a portal for that purchase does not change the practical result. Contract pharmacies purchase AbbVie's drugs at a state-mandated price and the State will civilly and criminally punish AbbVie if it does not complete the transfer at that price.

B. H.B. 1056's Taking is Coercive, Not Voluntary.

The district court glossed over this clear taking, focusing instead on its belief that H.B. 1056 "does not compel drug manufacturers to transfer their products" because "[t]he statute only applies to drug manufacturers who voluntarily participate in the Medicaid and Medicare programs."

JA876. Although the court appeared to be invoking the voluntary participation doctrine, it offered no analysis of why AbbVie's "participation" in Maryland's new regime is voluntary rather than compulsory. To be sure, the voluntary participation doctrine holds that the government, in issuing benefits, may attached certain conditions to those benefits. But that doctrine does not apply here for two separate reasons.

First, Maryland does not condition compliance with H.B. 1056 on anything the State itself offers. It instead demands manufacturers sell discounted products to pharmacies, on pain of criminal and civil penalties. There is no benefit of Maryland's that AbbVie can deny to avoid the penalties that H.B. 1056 carries. And AbbVie's ostensibly voluntary participation in the *federal* 340B Program does not mean that it has voluntarily chosen to participate in *Maryland*'s compulsory regime.

The one court that has confronted an issue like this agreed with AbbVie's position. *See Virginia Hosp. & Healthcare Ass'n v. Roberts*, 671 F. Supp. 3d 633 (E.D. Va. 2023). There, Virginia law required hospitals participating in federal Medicare or Medicaid to obtain a certificate of public need if they wanted to make certain updates to their facilities in

excess of a specified dollar amount. *Id.* at 644. Hospitals sued both the federal and state governments under the Takings Clause. The court determined that the *federal* government had no takings liability, because the hospitals voluntarily participated in the *federal* Medicaid and Medicare programs. But, as against the *state* government, the court concluded that Virginia compelled "any healthcare system with an acute care hospital in Virginia to participate in Medicare and Medicaid." That likely violated the Takings Clause because "[t]hose *state law* [certificate] requirements have no bearing on whether providers' participation in Medicaid and Medicare is voluntary as a matter of *federal* law." *Id.* at 666-67.[8]

Neither is it an answer to say that AbbVie can simply withdraw from the entire 340B Program. AbbVie's participation in Medicaid is already the predicate for its participation in the 340B Program—*i.e.*, Maryland offers nothing over and above what AbbVie already receives.[9]

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[8] The court ultimately concluded the state was immune from suit under the Eleventh Amendment for reasons not even arguably present here.

[9] On voluntariness, both the State's argument and the district court's conclusion stand only on reference to *federal* programs and requirements. That the State must draft off these federal programs to

"A voluntary exchange for a governmental benefit" "does not exist" "if the purported 'benefit' is illusory." *Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1232 (D.C. Cir. 2023). Distilled to its core, Maryland's "offer" amounts to nothing more than the pharmaceutical market in the State. But Maryland may not demand that AbbVie part with its constitutional property rights as a condition of engaging in commerce. *Horne*, 576 U.S. at 366. That is because participating in commerce is "not a special governmental benefit that the Government may hold hostage, to be ransomed by the waiver of constitutional protection." *Id.*

Second, even if this were treated as a traditional voluntary-participation-doctrine case, Maryland's law would fail because there is no nexus or rough proportionality between forced sales to pharmacies and AbbVie's decision to participate in federal programs.

The unconstitutional conditions doctrine "vindicates the Constitution's enumerated rights by preventing the government from

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justify its law reveals that the State is inappropriately meddling in a wholly federal universe. *See supra* at §I. But the State cannot have it both ways: H.B. 1056 cannot be wholly separate from the federal 340B Program while at the same time justified by virtue of the federal Program's alleged voluntariness.

coercing people into giving them up." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013). When evaluating whether the government has abused its power to add conditions to the receipt of a benefit, courts first ask "whether the condition would qualify as a taking if the government had directly required it." *Knight v. Metro. Gov't of Nashville & Davidson Cnty., Tenn.*, 67 F.4th 816, 825 (6th Cir. 2023). Absent voluntary agreement, it is beyond dispute that H.B. 1056's command to transfer property would constitute a taking.

The next two inquiries are (1) whether there is an "essential nexus" between the benefit's conditions and the governmental interest justifying those conditions and (2) whether the conditions on receiving the benefit bear a "rough proportionality" to the benefit's supposed impact on the governmental interest. *Sheetz v. Cnty. of El Dorado, Colo.*, 601 U.S. 267, 275 (2024). For example, "if a proposed development will 'substantially increase traffic congestion,' the government may condition the building permit on the owner's willingness 'to deed over the land needed to widen a public road.'" *Id.* at 274-75 (quoting *Koontz*, 570 U.S. at 605). These requirements recognize that a property owner threatened with certain conditions is "likely to accede to the government's demand, no matter how

unreasonable, so long as she values [the intended use of the property] more." *Id.* at 275 (internal quotation marks omitted). They serve to prevent "an out-and-out plan of extortion." *Id.*

H.B. 1056 fails at both steps. As a "condition" of AbbVie agreeing to provide significant price concessions to the federal government through various programs, Maryland demands it must now agree to extend those discounts to for-profit pharmacies in the State. But first, it is not clear what benefit Maryland is conferring on AbbVie in exchange for this obligation (and as discussed above, it cannot be mere participation in commerce). Even pretending for the sake of argument that Maryland can stand in the shoes of the federal government, there is no nexus between AbbVie's participation in a *federal* healthcare program that excludes for-profit pharmacies and Maryland's insistence that AbbVie transfer drugs to those same pharmacies.

Even less so is there a rough *proportionality* between AbbVie's participation in federal healthcare programs and Maryland's compelled-transfer demands. *See, e.g.*, *id.* at 276. There is, of course, no negative impact in Maryland from AbbVie selling discounted medications through federal government programs. Yet the State now offers nothing further

but seeks to extract even more from AbbVie by conditioning its involvement in *federal* programs on participation in the *State's* compulsory regime. It is one thing for Congress to set certain conditions, within reason, on a manufacturer's participation in Medicaid. It is something else altogether when a state leverages that participation to regulate constitutional rights "outside the contours of the program itself." *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 214-15, (2013).

The Fifth Amendment does not permit the State to wrench property from AbbVie and give it to another private party by pretending that transfer was a condition of participation in *federal* healthcare programs. Indeed, federal courts of appeals have made clear that existing federal programs do *not* require AbbVie to countenance such transfers as a condition of participation. *Novartis*, 102 F.4th at 461; *Sanofi*, 58 F.4th at 707.

C. H.B. 1056's Taking Is Not For Public Use.

H.B. 1056's compelled taking is not for "public use," so it cannot pass constitutional muster. The Fifth Amendment permits the government to appropriate an individual's property, subject to the limitation that the property be put to a "public use." U.S. Const. amend. V. Maryland's law requires that AbbVie transfer its products at significantly reduced prices to for-profit pharmacy chains that populate the Fortune 500. It is thus a taking for private rather than public use, and no compensation could cure the underlying constitutional injury.

The Supreme Court has consistently condemned the kind of private A-to-B property transfer Maryland attempts to work here. *See, e.g.*, *Calder*, 3 U.S. at 388 (describing that it is "against all reason and justice" for a law to "take property from A[] and give[] it to B"); *Haw. Hous. Auth. v. Midkiff*, 467 U.S. 229, 245 (1984) ("A purely private taking could not withstand the scrutiny of the public use requirement; it would serve no legitimate purpose of government and would thus be void."); *Kelo v. City of New London, Conn.*, 545 U.S. 469, 477 (2005) ("[I]t has long been accepted that the sovereign may not take the property of *A* for the sole

purpose of transferring it to another private party *B*, even though *A* is paid just compensation.").

Under this rubric, Maryland's compelled transfer of AbbVie's products to for-profit pharmacies cannot be a "public use." H.B. 1056 does not command that the state of Maryland will obtain the drugs for itself and pay for them. Instead, the *pharmacies*, without paying market value, will gain complete possession and control of the drugs until dispensed to their customers at full price. Indeed, the record demonstrates that even covered entities understand pharmacies to be taking title to the drugs, rather than covered entities. JA557. And the record indicates that these pharmacies often do not pass on the discounts they obtain to patients. *See* JA684, JA692, JA693; JA433.

By referring to H.B. 1056 as serving a broad public "purpose" rather than a public "use," the district court improperly extended the *Kelo* line of cases. In particular, the district court characterized the test as "whether the regulation serves a public purpose" and—as a part of that analysis—reasoned that it owed "great respect … to state legislatures … in discerning local public needs." JA875.

First, there is no reason that *Kelo* and its predecessors in *Midkiff* and *Berman v. Parker*, 348 U.S. 26 (1954)—which exist only in the narrow context of land use and blight abatement for specific public purposes—should be extended to these circumstances. Maryland's law compelling AbbVie to provide discounted drugs to for-profit pharmacies does not seek to rectify or redress any kind of "blight" as in *Berman*, 348 U.S. at 32, or "land oligopoly" as in *Midkiff*, 467 U.S. at 242. Nor is the taking executed pursuant to a carefully designed development plan as in *Kelo*. 545 U.S. at 483-84. Indeed, both *Kelo* and *Midkiff* recognized that laws like H.B. 1056 cross the constitutional line: the Court explained that "[s]uch a one-to-one transfer of property, executed outside the confines of an integrated development plan" was not in issue, but that such an "unusual exercise of government power would certainly raise a suspicion that a private purpose was afoot." *Kelo*, 545 U.S. at 487. There is no factual overlap at all between the *Kelo* line of cases and this one. Here, a state legislature intends to compel the transfer of personal property to other private parties at strict, below-market prices on pain of civil and criminal penalties. And in so doing, H.B. 1056 improperly singles out for preferential treatment a preferred class of private entities the state of

Maryland simply prefers over pharmaceutical manufacturers: commercial pharmacies.

Second, the district court also erred when it relied upon what it called the Supreme Court's "longstanding policy of deference to legislative judgment" in the Takings context to conclude that Maryland's law serves a public purpose. JA878. The problem with that is the Supreme Court's recent clarification that "special deference for legislative takings would have made little sense historically, because legislation was the conventional way that governments exercised their eminent domain power." *Sheetz*, 601 U.S. at 277. Indeed, "[f]ar from supporting [the] deferential view" of legislative takings, "history shows that legislation was a prime target for scrutiny under the Takings Clause." *Id.* at 277-78. And because of that mistaken deference, the district court conducted no analysis whatsoever on whether H.B. 1056 actually furthers a public use or purpose—despite AbbVie's testimonial and documentary evidence suggesting that it does not. JA684, JA692, JA693; JA433. That was error: the Takings Clause intends for courts to act as more than a mere rubber stamp on private-to-private takings.

Even if the *Kelo* precedents apply here, H.B. 1056 still fails because it does not satisfy any broad "public purpose." The record demonstrates that discounted drugs are commonly sold at full price to 340B patients and non-patients alike irrespective of their financial status. JA216 (¶ 5); JA765-768 (¶ 8); JA621-622. The pharmacies then retain the arbitrage profit *for themselves*, not the public. And they often do not pass any financial benefit on to needy patients, either in the form of lower-priced drugs, other programs, or uncompensated care. Oftentimes a covered entity uses the profit to build satellite or child sites in affluent areas, where they continue to obtain 340B-priced drugs but have simply increased the pool of "patients" with insurers capable of paying full price. JA490; JA520. In short, the profits and revenues of contract pharmacies and covered entities continue to balloon, at the expense of manufacturers and patients alike. JA427, JA431, JA437, JA442; JA462, JA466, JA468; JA533. None of that is what the Constitution or Supreme Court precedent means by "public use."

Still, the district court somehow concluded, without any apparent reasoning, that "the purpose of HB1056, to protect the continued operation of providers that count as covered entities" is "a cognizable

public purpose." JA878. But the district court did not reference, much less discuss, any of the evidence that AbbVie provided showing that the beneficiaries are H.B. 1056 are for-profit pharmacies rather than the public writ large. Indeed, the State's opposition brief to AbbVie's motion for a preliminary injunction did not even argue that H.B. 1056 does achieve a public use or purpose. This Court should not sanction the district court's unreasoned conclusion that a buy-low, sell-high scheme for Walgreens, CVS, and the like is a "public use" under the Fifth Amendment.

Finally, were there any doubt that H.B. 1056 is an unconstitutional taking under the modern doctrine, the original meaning and settled historical understanding place it beyond debate. The original meaning of "public use" limits takings to transfers to the government, or to a private entity that had a legal obligation to hold open the property to the public. *See* Ilya Somin, *The Grasping Hand* (2015) at 36 (explaining that the original meaning of the Takings Clause limits eminent domain power to circumstances where the recipient "has a legal obligation to allow the general public to use the land in question, as in the case of a public utility"); *see also* Eric R. Claeys, *Public-Use Limitations and Natural*

Property Rights, 2004 Mich. St. L. Rev. 877, 879 (2004) ("[W]hen the government assigns property to private owners not subject to a duty of public access and common-carrier regulation, it unconstitutionally takes private property for private uses.").

Cases from the Founding and around the time of Reconstruction both reflect this understanding. *See, e.g.*, *Vanhorne's Lessee v. Dorrance*, 2 U.S. 304, 312 (C.C.D. Pa. 1795); *Calder*, 3 U.S. at 388; *Memphis Freight Co. v. City of Memphis*, 44 Tenn. 419, 425 (1867); *Bankhead v. Brown*, 25 Iowa 540, 545 (1868). Significant legal thinkers from both of those eras also suggested that takings were limited to public "use" rather than any conceivably public "purpose." *See* John Locke, *Two Treatises of Government and A Letter Concerning Toleration,* ed. Ian Shapiro (Yale University Press, 2003), § 138; William Blackstone, *Commentaries on the Laws of England* (Chicago: University of Chicago Press, 1979 [1765]), 1:135; Thomas Cooley, *A Treatise on the Constitutional Limitations Which Rest Upon the Legislative Power of the States of the American Union* at 531 (Boston: Little, Brown, 1868).

D. The Regulatory Takings Doctrine Does Not Apply, But Even If It Does, AbbVie Still Prevails.

As an initial matter, the regulatory takings doctrine does not apply because H.B. 1056 works a physical appropriation of AbbVie's property. *See supra* § II.A. In *Horne*, for example, the Court considered a takings challenge to a federal regulation requiring raisin farmers to set aside a percentage of their crop for disposition by a federal agency. The agency could then do with the raisins what it wished: sell them to private parties, donate them, release them to other growers, or simply dispose of them. *Horne*, 576 U.S. at 355. Though the raisin farmers retained an interest in any residual proceeds from sales of the raisins, the Court held this was a "clear physical taking," not merely a regulatory restriction on use, because the Government took "actual … possession and control" of the raisins. *Id.* at 360-62.

In a similar way, H.B. 1056 does not merely affect the way that AbbVie uses its own property—it requires that AbbVie actually give up its property to for-profit pharmacies who wish to "acqui[re]" it. H.B. 1056, § 12-6C-09.1(C)(1). That constitutes a physical taking even if the transfer occurs at the behest of a state law or under the fiction that a covered entity is the one really doing the ordering. H.B. 1056 forces

AbbVie to transfer its drugs to another private party, and it thus effects a physical appropriation of private property. *See Cedar Point*, 594 U.S. at 149.

Even if H.B. 1056 does constitute a regulatory taking, AbbVie satisfies the *Penn Central* test that governs. Under that test, courts decide whether a regulation of property "goes too far" by considering (1) the economic impact of the regulation, (2) the extent to which the regulation has interfered with investment backed expectations, and (3) the "character of the governmental action." *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978).

First, H.B. 1056 has a significant impact on AbbVie's property. The law requires AbbVie to transfer millions of dollars in discounted drugs to commercial pharmacies or face significant penalties. "Because H.B. 1056 requires AbbVie to provide its drugs at steeply discounted 340B prices to an unlimited number of contract pharmacy arrangements, AbbVie will face the threat of millions of dollars in forced unnecessary discounts each year as a result of H.B. 1056." JA178 (¶ 20). The district court's conclusion that H.B. 1056 is not "onerous" enough to constitute a

regulatory taking is hard to reconcile with the multimillion-dollar burden that it imposes. JA876.

Second, H.B. 1056 interferes with AbbVie's investment-backed expectations. AbbVie invests in developing and manufacturing lifesaving drugs to sell them, generating profits that enable further investment into the development of more lifesaving and life-improving products. *See* JA178 (¶ 18). H.B. 1056 interferes with AbbVie's investment-backed expectations by compelling AbbVie to transfer them to non-covered entities for pennies on the dollar. That necessarily inhibits AbbVie's ability to invest in the development of new drugs that improve patients' lives.

The district court observed that the history of the 340B Program "and litigation surrounding it suggest that regulations requiring delivery and forbidding restrictions against delivery to contract pharmacies were foreseeable." JA877. Again, that claim is difficult to reconcile with reality. At the time of H.B. 1056's enactment, AbbVie had a policy in place of limiting transfer of 340B drugs to contract pharmacies, while allowing hospital covered entities to designate one contract pharmacy within 40 miles. JA193-194. That policy is consistent both with the 340B

Program's historical practice and controlling federal precedents. The 340B Program operated under guidance permitting no more than one contract pharmacy per covered entity for the first 18 years of its existence. 61 Fed. Reg. at 43550-43555. When HRSA attempted to expand manufacturers' obligations under the Program and claimed that manufacturers must serve an unlimited number of contract pharmacies, *see supra* Advisory Opinion 20-06 at 3, courts of appeals uniformly rejected that effort, *see Sanofi*, 58 F.4th at 706; *Novartis*, 102 F.4th at 463-64. It is therefore inexplicable to conclude that AbbVie, through its years of research of development, should have known that state would thrust sweeping contract-pharmacy obligations upon it.

Third, the character of the government action here counsels in favor of finding a regulatory taking because it "amounts to a physical invasion" rather than simply "adjusting the benefits and burdens of economic life to promote the common good." *Lingle*, 544 U.S. at 539. H.B. 1056 compels the actual, physical transfer of AbbVie's private property to commercial pharmacies—an obligation the 340B Program itself does not impose. Worse, it offends the fundamental constitutional principle that the government may not "forc[e] some people alone to bear public

burdens which, in all fairness and justice, should be borne by the public as a whole." *Penn Central*, 438 U.S. at 123 (quoting *Armstrong*, 364 U.S. at 49).

III. PhRMA And Novartis Are Likely To Succeed On Their Claims That H.B. 1056 Violates The Extraterritoriality Principles In The United States Constitution.

Maryland's law also violates the dormant Commerce Clause and the constitutional bar on extraterritorial regulation. Under the Commerce Clause, Congress may regulate commerce among the several states. U.S. Const. art. I, § 8, cl. 3. Courts also recognize a "dormant" aspect of the Clause—a principle reflected in the Constitution's structural guarantee that "all States enjoy equal sovereignty." *Shelby Cnty., Ala. v. Holder*, 570 U.S. 529, 535 (2013); *see also State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422 (2003) ("A basic principle of federalism is that each State may make its own reasoned judgment about what conduct is permitted or proscribed within its borders[.]").

Consistent with these principles, a law may not "directly regulate[ ] out-of-state transactions by those with *no* connection to the State." *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 376 n.1 (2023).[10]

H.B. 1056 violates the dormant Commerce Clause in three ways.

A. H.B. 1056 Is Unlawfully Extraterritorial.

First, the statute purports to regulate conduct that occurs entirely outside Maryland. "[A] state may not regulate commerce occurring wholly outside of its borders." *Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664, 667 (4th Cir. 2018) (citation omitted). A law violates this extraterritoriality principle if it applies to transactions that occur entirely out-of-state or has the "practical effect" of doing so, "regardless of the legislature's intent." *Id.* at 668.

In *Association for Accessible Medicines*, this Court held that a Maryland law prohibiting a manufacturer or wholesaler from "price

[10] That principle is reinforced by several Constitutional provisions. States are denied certain powers that a sovereign might ordinarily impose, U.S. Const. art. I, § 10; and required to honor certain rights of other states, U.S. Const. art. IV, § 1, § 2, cl. 1-2, §3. Similarly, the Due Process Clause limits a state's ability to regulate conduct occurring wholly outside its borders. *See Watson v. Emps. Liab. Assurance Corp.*, 348 U.S. 66, 70 (1954); *Home Ins. Co. v. Dick*, 281 U.S. 397, 407-08 (1930).

gouging" in the sale of prescription drugs violated the dormant Commerce Clause. *Id.* at 674. Like H.B. 1056, the statute in *Frosh* targeted manufacturers and wholesalers, both of which were largely located out of state. *Id.* at 667. Thus, the "vast majority" of transactions covered by the Maryland statute occurred outside Maryland. *Id.*

The law in *Frosh* was, "by its own terms, not fixated on the price the Maryland consumer ultimately pa[id] for the drug. Instead, the lawfulness of a price increase [was] measured according to the price the manufacturer or wholesaler charge[d] *in the initial sale of the drug*." *Id.* at 671. This Court therefore held that the statute impermissibly targeted upstream, out-of-state transactions: "[T]he Act is effectively a price control statute that instructs manufacturers and wholesale distributors as to the prices they are permitted to charge in transactions that do not take place in Maryland." *Id.* at 672. *See also Pharm. Rsch. & Mfrs. of Am. v. D.C.*, 406 F. Supp. 2d 56, 68, 70 (D.D.C. 2005), *aff'd sub nom. Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007) (invalidating state drug-pricing law on dormant Commerce Clause grounds where drug manufacturers were located, and transactions occurred, wholly outside the District of Columbia).

Like the manufacturers in *Frosh*, Plaintiffs typically sell their products to wholesalers and distributors around the country, who then sell those products to national pharmacy chains, whose headquarters are also usually outside Maryland. JA038 (¶ 29), JA051 (¶ 66); JA106 (¶ 104); JA371-372 (¶ 2), JA403 (¶ 110). Only further down the drug distribution chain do any drugs make it to Maryland residents. JA051 (¶ 66). H.B. 1056 thus targets the manufacturers' upstream pricing and sale of the products to wholesalers, which typically takes place outside Maryland. Accordingly, the statute "compel[s] manufacturers and wholesalers to act in accordance with Maryland law outside of Maryland." *Frosh*, 887 F.3d at 672. That is unconstitutional. *Id.* at 671-672.

In upholding H.B. 1056, the district court sidestepped *Frosh* in three ways. JA893. It took the view that (1) H.B. 1056 is not triggered by out-of-state conduct and (2) does not directly control the prices of out-of-state transactions, and that (3) the enactment of similar statutes would not significantly burden interstate commerce involving prescription medications. JA893. But all roads lead back to the same

result this Court reached in *Frosh*: Here, as there, Maryland's law violates the dormant Commerce Clause.

First, H.B. 1056 *is* triggered by conduct outside Maryland. The district court ruled that the statute's requirement is triggered by an order or claim placed by a 340B covered entity in Maryland, despite that limitation being absent from H.B. 1056's text. JA893. Not so. Covered entities seeking 340B pricing seldom request or receive the price directly from drug manufacturers. JA038-039 (¶ 30). Instead, they purchase drug products, and obtain the 340B price, from out-of-state wholesalers and retailers. JA038-039 (¶¶ 29–30). The wholesalers then separately submit chargebacks to largely out-of-state manufacturers. JA038-039 (¶ 30). The law's mandate to apply 340B pricing to any 340B transaction involving any Maryland contract pharmacy directly impacts the chargeback a wholesaler submits to the manufacturer—a transaction typically taking place outside Maryland.

Below, the State appeared to concede it could not regulate activities occurring outside Maryland. In an effort to save H.B. 1056, the State suggested that H.B. 1056 did not apply to out-of-state covered entities, but also suggested it somehow simultaneously covered out-of-state

contract pharmacies.[11] JA262 ("I guess I'd feel confident in saying if the law was construed to apply to covered entities outside of Maryland, I think we might have an extraterritoriality problem[.]"). The State's admission does not go far enough. Even limiting H.B. 1056 to 340B-priced drugs that ultimately are purportedly "purchased" by Maryland covered entities, multiple transactions would occur outside of Maryland entirely, including the ultimate dispensing from an out-of-state pharmacy. The reasoning in *Frosh*, 887 F.3d 664, is applicable here and mandates that H.B. 1056 is unconstitutional. Even under the Attorney General's rewrite of H.B. 1056, which still purports to cover out-of-state pharmacies and customers, it remains infirm.

Second, Maryland's law controls the prices of out-of-state transactions. The district court thought otherwise, stating H.B. 1056 does not set the terms of transactions between manufacturers and wholesalers, even if it impacts manufacturers' decisions in negotiating out-of-state sales with wholesalers. JA894. But the statute inherently sets those terms. By not allowing manufacturers to "restrict" or

[11] The term "pharmacy" contains no geographic limitation.

"otherwise limit the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with … a covered entity," H.B. 1056, § 12-6C-09.1(C)(1), H.B. 1056 requires a manufacturer to give 340B pricing on any 340B transaction involving any Maryland contract pharmacy. This requirement directly affects the chargeback a wholesaler seeks from a manufacturer, in a transaction between two out-of-state entities. Maryland's statute therefore dictates that manufacturers give particular pricing on wholly out-of-state transactions. That violates the dormant Commerce Clause.

Third, the proliferation of statutes like Maryland's will compound the burden on interstate commerce. The district court speculated that similar enactments would not interfere with one another to burden interstate commerce and that they may actually lessen any compliance burden. JA894-895. The court below got the patchwork effect exactly backwards: "As a practical matter, complying with" the federal government's "detailed regulatory regime in the shadow of 50 States' " competing state-law frameworks "will dramatically *increase* the burdens facing" drug manufacturers. *Buckman*, 531 U.S. at 350 (emphasis added). With each new statute, a drug manufacturer must ensure that

its practices in that particular state would not subject it to civil or criminal liability. *See id.* "If other states were to follow suit, it would jeopardize what the dormant Commerce Clause aims to preserve: 'a national [free] market for competition undisturbed by preferential advantages conferred by [individual] State[s] upon [their] residents or resident competitors.'" *Yamaha Motor Corp., U.S.A. v. Jim's Motorcycle, Inc.*, 401 F.3d 560, 573-574 (4th Cir. 2005) (alterations in original) (citation omitted).

B. H.B 1056 Has Discriminatory Purpose And Effect.

At the "very core" of the Clause is a simple "antidiscrimination principle": A state may wish to enact "regulatory measures designed to benefit in-state economic interests," but its legislation cannot engage in "economic protectionism" by privileging its homegrown commercial interests while "burdening out-of-state competitors." *Pork Producers*, 598 U.S. at 369. A law that discriminates against out-of-state economic entities thus violates the Commerce Clause unless it is "narrowly tailored to advance a legitimate local purpose," and there is no reasonable nondiscriminatory alternative. *Tenn. Wine & Spirits Retailers Ass'n v. Thomas*, 588 U.S. 504, 505, 514 (2019) (dormant Commerce Clause

principles "prevent[] the States from adopting protectionist measures and thus preserve[] a national market for goods and services"). Laws may discriminate against interstate commerce facially, in their practical effect, or in their purpose. *Colon Health Ctrs. of Am., LLC v. Hazel*, 813 F.3d 145, 154 (4th Cir. 2016).

H.B. 1056 unlawfully discriminates in both purpose and effect by privileging the *in-state* economic interests of covered entities and pharmacies at the expense of *out-of-state* manufacturers. The purpose of Maryland's law is to protect the economic interests of in-state hospitals and pharmacies over those of out-of-state manufacturers, placing heavy burdens on manufacturers to fill the coffers of those in-state entities. H.B. 1056 prevents manufacturers from placing reasonable restrictions on contract-pharmacy arrangements that drive up 340B pricing, ensuring that the resulting payout will be reaped by covered entities, contract pharmacies, and third-party administrators—not passed on to the patients. *Novartis*, 102 F.4th at 457-458. The statute thus privileges those who receive the 340B benefit (in-state hospitals and pharmacies) at the expense of those who must comply with the requirement (out-of-state manufacturers).

The district court found the "apparent purpose" of H.B. 1056 is to increase the accessibility of 340B drugs to Maryland patients in need. JA896. But it never squared this conclusion with the nature of the transactions at issue. Drug manufacturers already deliver these drug products to Maryland pharmacies, and the patients rarely see any savings: They pay the same on their prescriptions either way. JA233, JA280. The law therefore intends not to increase the number of drug deliveries to pharmacies or to reduce the price that patients pay but rather to increase the funds available to commercial pharmacies.

Maryland's law also has discriminatory effect: H.B. 1056 compels out-of-state manufacturers to provide their products at 340B-discounted prices to Maryland hospitals and pharmacies in an unlimited number of transactions. In *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935), the Supreme Court explained that the Commerce Clause does not allow a state to create a "[scale] of prices for use in other states, and to bar the sale of the products, … unless the scale has been observed." *Novartis*, 102 F.4th at 503. But that is exactly what H.B. 1056 does: It sets a scale of drug prices for use by out-of-state manufacturers in any 340B transaction involving a Maryland contract pharmacy and subjects an out-

of-state manufacturer's drugs to 340B pricing on a whole host of transactions that would otherwise not be 340B-eligible.

H.B. 1056 thus requires manufacturers to apply 340B ceiling prices to transactions involving Maryland contract pharmacies. That is price-setting. The law does not merely prevent "delivery manipulation"; that much is apparent from its terms, which nowhere impose conditions on drug deliveries, such as labeling requirements for shipments. Defs. Opp'n to Mot. for Prelim. Inj. (No. 24-1557, ECF 26) at 27. The law instead regulates drug pricing, mandating the 340B discount be applied limitlessly to transactions involving Maryland contract pharmacies. H.B. 1056 discriminates against out-of-state manufacturers in purpose and effect, is anything but narrowly tailored, and ignores reasonable alternatives.

C. H.B. 1056 Excessively Burdens Interstate Commerce.

A statute will not be upheld if its burden on interstate commerce is "clearly excessive" in relation to its "putative local benefits." *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). This analysis considers the "nature of the local interest involved" and "whether it could be promoted as well with a lesser impact on interstate activities." *Id.*

The burdens that Maryland's law imposes on interstate commerce are clearly excessive in relation to the putative local benefits. Under H.B. 1056, drug manufacturers cannot impose *any* contract-pharmacy limits on their 340B-drug transactions: If a Maryland covered entity contracts with a thousand contract pharmacies, a manufacturer must give 340B pricing on all transactions for which the discount is sought. Maryland insists this legislation helps uninsured and underinsured Marylanders afford costly medications. Defs. Opp'n to Mot. for Prelim. Inj. (No. 24-1557, ECF 26) at 10. But again, even assuming the medication is dispensed to a Maryland patient from a Maryland contract pharmacy, H.B. 1056 does not help needy Marylanders afford drug products; the 340B discount is given on the back end, *after* a prescription has already been dispensed to the patient. *See* JA174-175 (¶ 7); JA216 (¶¶ 4–6); JA215-218 (¶¶ 3–11); JA765-767 (¶8a–d).

All of this means that Maryland lacks a valid justification for excessively burdening interstate commerce. The putative local benefit to patients is minimal at best—the law lines the pockets of Maryland covered entities, pharmacies, and third-party administrators, not uninsured and underinsured Maryland patients. Maryland's

justification thus is divorced from the reality of 340B transactions and cannot justify the heavy burden placed on drug manufacturers. *Cf. Yamaha*, 401 F.3d at 570-571 (This Court has "doubted a statute's putative benefits … [where] the purported ruinous effects of competition that a statute aimed to combat were entirely speculative." (internal quotation marks omitted) (citation omitted)).

Even if Maryland had a legitimate and demonstrable purpose, moreover, the State could advance that purpose "with a lesser impact on interstate activities." *Pike*, 397 U.S. at 142. Maryland could, for example, give grants directly to covered entities and pharmacies serving uninsured or underinsured patients. Maryland argued below that providing such grants would not achieve H.B. 1056's goal of "preventing limits or restrictions on the acquisition or delivery of 340B drugs." Defs. Opp'n to Mot. for Prelim. Inj. (No. 24-1557, ECF 26) at 28. But a grant would accomplish the same end that Maryland invokes to defend H.B. 1056: It would give covered entities funding to use "as they see fit" so they could treat more patients and offer more services. *Id.* at 4. H.B.1056's "unnecessary and excessive breadth" establishes that "the statute's burdens clearly exceed its benefits." *Yamaha*, 401 F.3d at 573.

Even though Congress "evidently believed" it would be "undesirable" to forbid any reasonable limits on contract-pharmacy use, H.B. 1056 "would allow states to bring about something very close to that result." *Omega World Travel, Inc. v. Mummagraphics, Inc.*, 469 F.3d 348, 355 (4th Cir. 2006); *see also Sanofi*, 58 F.4th at 707; *Novartis*, 102 F.4th at 464. As more states follow Maryland's lead, drug manufacturers will bear increasingly higher costs to comply with the growing patchwork of distinct state contract-pharmacy statutes. As explained above, this compliance burden is not lessened as more states enact similar statutes. *Supra* at 90. Rather, a slew of enactments would submit a national regulatory program to the whims of state-by-state legislation. That not only ratchets up compliance costs for out-of-state manufacturers that must compete in a national marketplace but also frustrates the aims of the dormant Commerce Clause. H.B. 1056's weighty burdens clearly exceed its merely speculative benefits.

IV. APPELLANTS HAVE SATISFIED THE REMAINING INJUNCTION FACTORS.

The district court focused its analysis on the "likelihood of success" prong—it did not reach the "irreparable harm" factor, and it only briefly considered whether a balancing of the equities favored a preliminary

injunction. This Court "must perform [its] own assessment of the factors not addressed by the district court" to review the bottom-line decision to deny injunctive relief. *In re Search Warrant Issued June 13, 2019*, 942 F.3d 159, 171 (4th Cir. 2019). Appellants easily satisfy each of the remaining factors.

A. Enforcement Of H.B. 1056 Would Irreparably Harm Appellants.

Appellants will suffer irreparable harm absent an injunction. Most importantly, Appellants would remain subject to a state regime that unconstitutionally requires them to provide vast quantities of heavily discounted drugs. The deprivation of constitutional rights generally constitutes irreparable harm. *See Leaders of a Beautiful Struggle v. Balt. Police Dep't*, 2 F.4th 330, 346 (4th Cir. 2021) (en banc). And once taken, possession of Appellants' drugs resides with for-profit pharmacies until they are dispensed. There is no possible "just compensation" for a private taking like H.B. 1056—such takings are *per se* unconstitutional. *Thompson v. Consol. Gas Utils. Corp.*, 300 U.S. 55, 80 (1937). Moreover, the prospect that Maryland will enforce a likely preempted state law against Appellants "supplies the necessary irreparable injury" to justify injunctive relief. *See Air Evac EMS, Inc. v. McVey*, 37 F.4th 89, 103 (4th

Cir. 2022) (quoting *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381-82 (1992)).

In addition, Appellants will continue to suffer significant financial harm because of H.B. 1056. In complying with Arkansas's similar law, for example, AbbVie will incur approximately $15.3 million in compliance costs between May and December 2024. JA768 (¶ 9). "[C]omplying with a regulation later held invalid almost *always* produces the irreparable harm of nonrecoverable compliance costs." *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 229-21 (1994) (Scalia, J., concurring in part); *see also Morrisey*, 2024 WL 5147643, at *14 ("[B]eing subjected to fines and being forced to spend resources on compliance with a law ultimately struck down has been sufficient to meet irreparable harm."). That is in addition to the millions of dollars in forced unnecessary discounted pricing Appellants will incur because of H.B. 1056. JA178 (¶ 20). Importantly, even if Appellants are ultimately successful in their constitutional challenges, Appellants would be unable to recover damages from Maryland for their expenditures. *See Edelman v. Jordan*, 415 U.S. 651, 662-63 (1974) (holding the Eleventh Amendment shields states from attempts to recover wrongfully withheld funds).

B. Enjoining H.B. 1056 Is In The Public Interest.

Appellants have also demonstrated that the public interest would be served by enjoining H.B. 1056. *See* JA896-897. Because the State is the opposing party, the last two factors—balance of the equities and public interest—merge together. *Nken v. Holder*, 556 U.S. 418, 434-35 (2009). Maryland "is in no way harmed by issuance of a preliminary injunction which prevents [its officers] from enforcing restrictions likely to be found unconstitutional." *Beautiful Struggle*, 2 F.4th at 346 (quoting *Centro Tepeyac v. Montgomery County*, 722 F.3d 184, 191 (4th Cir. 2013) (en banc)).

Nor would enjoining H.B. 1056 negatively affect disadvantaged patients' access to drugs, as the district court assumed. *See* JA896. The manufacturer policies H.B. 1056 targets do not deny access to drugs. Manufacturers provide drugs to the same pharmacies at issue here, just at commercial prices, and these are the same prices that the patient will pay even under the Maryland statute. *See* JA123 (¶ 11); JA128-129 (¶ 10); *see also* JA537, JA545 (discussing that even on discounted drugs, the discounts are rarely passed on to patients). Enjoining these restrictions will merely limit the ability of commercial pharmacies to line

their pockets at manufacturers' expense. *See, e.g.*, JA684; JA692-693; JA429; JA544-546.

Finally, a "preliminary injunction [would do] nothing to upset the federal program." *Morrisey*, 2024 WL 5147643, at *15. Given that "HHS retains its power to enforce under its authority granted by Congress," the federal government can still police Appellants' "obligations under the 340B Program." *Id.* A preliminary injunction would merely "keep[] the parties in their respective conditions prior to [H.B. 1056's] enactment." *Id.*

CONCLUSION

The district court's order denying a preliminary injunction should be reversed.

STATEMENT REGARDING ORAL ARGUMENT

Pursuant to Federal Rule of Appellate Procedure 34(a)(1) and Fourth Circuit Rule 34(a), Appellants respectfully request oral argument. This consolidated appeal presents complex and important constitutional questions about the about the extent to which state legislatures may rework the federal 340B scheme to their own ends—questions courts and legislatures are grappling with nationwide. Appellants respectfully submit that oral argument will assist the Court in resolving this matter.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) and Fourth Circuit Rule 32(b), as modified by this Court's Order Granting Motion to Exceed Length Limitations (ECF 30), because it contains 19,440 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

This brief also complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Century font 14-point type face.

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CERTIFICATE OF SERVICE

This is to certify that the foregoing brief has been served via the Court's CM/ECF filing system in compliance with Rule 25(b) and (c) of the Federal Rules of Appellate Procedure, on December 18, 2024, on all registered counsel of record, and has been transmitted to the Clerk of the Court.

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STATUTORY ADDENDUM

Page

MD Code, Health Occupations, § 12-6C-09.1

(a)(1) In this section the following words have the meanings indicated.

(2) "Covered entity" has the meaning stated in 42 U.S.C. § 256b(a)(4).

(3) "Package" has the meaning stated in 21 U.S.C. § 360eee(11).

(4)(i) "340B drug" means a drug that:

1. Is a covered outpatient drug under 42 U.S.C. § 256b;

2. Has been subject to an offer for reduced prices by a 340B manufacturer under 42 U.S.C. § 256b(a)(1); and

3. Is purchased by a covered entity.

(ii) "340B drug" includes a drug that would have been purchased but for the limitation under subsection (c) of this section.

(5) "340B manufacturer" means a manufacturer, as defined in 42 U.S.C. § 1396r-8(k)(5), of covered outpatient drugs that has signed a pharmaceutical pricing agreement under 42 U.S.C. § 256b(a)(1).

(b) This section may not be construed to be:

(1) Less restrictive than any federal law that is applicable to a person regulated by this section; or

(2) In conflict with applicable federal and State laws and regulations.

(c)(1) Except as provided in paragraph (2) of this subsection, a 340B manufacturer may not directly or indirectly deny, restrict, prohibit, discriminate against, or otherwise limit the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with or otherwise authorized by a covered entity to receive 340B drugs on behalf of the covered entity unless the receipt of 340B drugs is prohibited by the U.S. Department of Health and Human Services.

(2) A 340B manufacturer may limit the distribution of a 340B drug if the limitation is required under 21 U.S.C. § 355-1.

(d)(1)(i) A violation of subsection (c) of this section:

1. Subject to paragraph (2) of this subsection, is an unfair, abusive, or deceptive trade practice within the meaning of Title 13 of the Commercial Law Article and is subject to the enforcement and penalty provisions contained in Title 13 of the Commercial Law Article; and

2. A. If the alleged violation was committed by a person that is licensed or permitted by the Board, shall be investigated by the Board or the Consumer Protection Division of the Office of the Attorney General; or

B. If the alleged violation was committed by a person that is not licensed or permitted by the Board, shall be investigated by the Consumer Protection Division of the Office of the Attorney General.

(ii) As part of an investigation conducted under subparagraph (1)(i)2 of this paragraph, the Board or the Consumer Protection Division of the Office of the Attorney General may investigate an affiliate or a contractor of the 340B manufacturer, including a wholesaler or third-party logistics provider.

(2)(i) In addition to the penalties under Title 13 of the Commercial Law Article, a civil fine may be assessed in the amount of $5,000 per violation of subsection (c) of this section.

(ii) A violation of this section does not create a private right of action under § 13-408 of the Commercial Law Article.

(3) If a violation of subsection (c) of this section is committed by a person licensed or permitted by the Board, the Board may impose discipline, suspension, or revocation of the person's license or permit.

(4) Each package of 340B drugs subject to a violation of subsection (c) of this section shall constitute a separate violation.